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HEALTH TECHNOLOGY CASE STUDY 31

The Contact Lens Industry

Structure, Competition, and Public Policy

DECEMBER 1984

This case study was performed as part of OTA's Assessment of

Federal Policies and the Medical Devices Industry

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Preface

The Contact Lens Industry: Structure, Competition, and Public Policy is Case Study 31 in OTA's Health Technology Case Study Series. This case study has been prepared in connection with OTA's project on *Federal Policies and the Medical Devices Industry*, which was requested by the Senate Committee on Labor and Human Resources and endorsed by the Senate Committee on Veterans' Affairs. A listing of other case studies in the series is included at the end of this preface.

OTA case studies are designed to fulfill two functions. The primary purpose is to provide OTA with specific information that can be used in forming general conclusions regarding broader policy issues. The first 19 cases in the Health Technology Case Study Series, for example, were conducted in conjunction with OTA's overall project on *The Implications of Cost-Effectiveness Analysis of Medical Technology*. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of cost-effectiveness or cost-benefit analysis, OTA was able to better analyze the potential contribution that those techniques might make to the management of medical technology and health care costs and quality.

The second function of the case studies is to provide useful information on the specific technologies covered. The design and the funding levels of most of the case studies are such that they should be read primarily in the context of the associated overall OTA projects. Nevertheless, in many instances, the case studies do represent extensive reviews of the literature on the efficacy, safety, and costs of the specific technologies and as such can stand on their own as a useful contribution to the field.

Case studies are prepared in some instances because they have been specifically requested by congressional committees and in others because they have been selected through an extensive review process involving OTA staff and consultations with the congressional staffs, advisory panel to the associated overall project, the Health Program Advisory Committee, and other experts in various fields. Selection criteria were developed to ensure that case studies provide the following:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (e.g., general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (e.g., cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide information material relating to the broader policy and methodological issues being examined in the particular overall project; and
- examples with sufficient scientific literature.

Case studies are either prepared by OTA staff, commissioned by OTA and performed under contract by experts (generally in academia), or written by OTA staff on the basis of contractors' papers.

OTA subjects each case study to an extensive review process. Initial drafts of cases are reviewed by OTA staff and by members of the advisory panel to the associated project. For commissioned cases, comments are provided to authors, along with OTA's suggestions for revisions. Subsequent drafts are sent by OTA to numerous experts for review and comment. Each case is seen by at least 30 reviewers, and sometimes by 80 or more outside reviewers. These individuals may be from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists, sociologists, decision analysts, biologists, and so forth, as appropriate, also review the cases.

Although cases are not statements of official OTA position, the review process is designed to satisfy OTA's concern with each case study's scientific quality and objectivity. During the various stages of the review and revision process, therefore, OTA encourages, and to the extent possible requires, authors to present balanced information and recognize divergent points of view.

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[d]Background Paper #3 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[e]Background Paper #5 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[f]Background Paper #1 to OTA's May 1982 report *Technology and Handicapped People*.

[g]Background Paper #2 to *Technology and Handicapped People*.

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OTA Note

These case studies are authored works commissioned by OTA. Each author is responsible for the conclusions of specific case studies. These cases are not statements of official OTA position. OTA does not make recommendations or endorse particular technologies. During the various stages of review and revision, therefore, OTA encouraged the authors to present balanced information and to recognize divergent points of view.

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1.
Summary

1. Summary

This study presents an analysis of the contact lens industry in the United States, emphasizing the role of economics and public policy in shaping past and future development. The analysis follows the general format usually employed in such industry studies: 1) the evolution and present configuration of the structural and institutional features, including public policy, that define the contact lens industry; 2) the corporate strategies and policies conditioned by this operational context; and 3) the end results of these strategies and policies in terms of the technical improvement of contact lenses, the ways of making them, and the prices at which they are sold.

In following this general format, the study is both descriptive and analytical. The descriptive aspects include the historical evolution of contact lenses (ch. 2); the range of available lens types (ch. 3); the characteristics of wearers of contact lenses, how much they spend, and the sources of payment for these contact lenses expenditures (ch. 4); the firms that make contact lenses (ch. 5); the eye-care professionals who represent the bridge between makers and users by prescribing and fitting contact lenses, and toward whom lens manufacturers direct most of their marketing efforts (ch. 6); and the regulatory context within which the entire manufacturing and selection process takes place (ch. 7).

The first part of the analysis relates structure to behavior, or the influence that the number, size, market power, and policies of the makers of contact lenses have on their incentives and behavior regarding competition in product development and price.

The second part of the analysis focuses on the role played by public policy in influencing this competition, either directly or indirectly. The more important elements of public policy affect: 1) mergers, 2) market entry, 3) competition in the professional prescribing and fitting of contact lenses, and 4) the payment mechanism in the purchasing process.

Why is it important to know these features of the contact lens industry and how public policy affects the industry's operation, when the industry is quite small, with annual domestic sales at the manufacturers' level currently running about $350 million? First, the analysis of any industry, however small, provides another economic case study that adds to our knowledge of how industry structure and public policy affect the competitive behavior of firms in the marketplace. Second, the contact lens industry gives every indication of growing considerably in the relatively near future; thus, its record in product improvement and pricing will be increasingly important relative to the full range of goods and services produced in the economy. Third, the study of the effects of public policy regarding the contact lens industry can provide guidelines for the formulation of sound policies in the future toward this industry, and, in turn, by serving as a case study, for the formulation of effective policies to influence the activities and performance results of other industries, both inside and outside the medical sector.

Contact lenses are of three types, although the distinctions between the types could conceivably disappear in the future. The first type of modern contact lens was the hard "PMMA" (for "polymethylmethacrylate") lens, made of plexiglass-type plastics. The advantages of this type are relative rigidity (where flexing may be a problem), smallness, lightness, safety (minimal risk to the eyes), ease of precision-machining, ease of maintenance, and durability. Their major disadvantage is that they are impermeable to oxygen and interfere with the flow of oxygen to the cornea. For a sizable proportion of potential wearers, this problem may actually deter the wearing of PMMA lenses; for others, wearing time becomes limited to a usual daily maximum of 8 to 16 hours. PMMA lens wearers may also incur "spectacle blur" when switching from lenses to glasses.

The second type of contact lens is made from water-absorbing plastics called "hydrogels" (mostly

"HEMA"—for "hydroxyethylmethacrylate"—hydrogels, but other hydrogel materials are also popular) or soft silicone. Their water absorbency and resulting softness make them considerably more easy to adapt to and more comfortable for longer periods, but the same characteristics make them fragile, provide less acute vision correction, and may increase the likelihood of eye infections from handling and wearing.

The third type of lenses is gas permeable. These lenses have much of the superior optical and ease-of-care qualities of hard lenses because of their rigidity, and the comfort of soft lenses because they are oxygen permeable.

About 120 million people in the United States wear corrective eyeglasses and another 16 million to 18 million use contact lenses, either exclusively or interchangeably with eyeglasses. Among all U.S. contact lens wearers, the use of hard lenses is declining and the use of soft and gas permeable lenses is increasing. For new fittings, hard lenses represent a minor share, soft lenses predominate, and gas permeables are the fastest growing. For both new fittings and replacements together, soft lenses represent upwards of 75 percent of the total market, probably their peak figure. Hard lenses have 15 percent or less of the market, and gas permeables at least 10 percent.

In the future, soft and gas-permeable lenses will account for almost all lens sales, perhaps about equally. There are some signs that a hybrid type of lens, combining the best qualities of each type, may be emerging. If so, then this fourth type will be "the" contact lens of the future. Whether or not this hybrid is developed, contact lenses may become as common or even more common a method of vision correction than eyeglasses, as their comfort, wearability, applications, and effectiveness continue to increase.

At present, contact lenses are particularly useful in the correction of single vision problems, essentially myopia (nearsightedness) and hypermetropia (farsightedness). They are also useful in the correction of astigmatism (a vision defect usually resulting from an irregular, nonsymmetrical conformation of the cornea, which results in a lack of sharpness or evenness of focus) and presbyopia (the loss of flexibility in refocusing from near to far objects, and vice versa) for which bifocal or multifocal corrective lenses or monovision correction is employed. These "disorders of refraction and accommodation" rank very high among physical problems, as evidenced by patient visits to all eye-care professional practitioners.

Certain interesting features exist in the pattern of contact lens wearers. Unlike eyeglasses, contact lenses have been a "younger person's" product. The traditional wearer has been the young adult female. However, as the therapeutic applications of contact lenses expand and consumer tastes are altered (partly by increased direct advertising by manufacturers), contact lens usage among males and among older persons is increasing rapidly and the traditional orientation toward the young adult female is disappearing.

The absolute price of contact lenses of all types has fallen significantly in the past decade, a time of high general inflation. Soft lens wholesale prices now are about half their mid-1970s level, and total fitting prices are half or less of their early 1970s level. Lens price reductions have resulted from large-scale entry, excess capacity, and vigorous price competition among manufacturers, particularly in the soft lens group. Total-fitting price reductions reflect these cuts in lens prices and the expanded competition among lens fitters, particularly the large chain optical houses. Continued price competition is likely, and further price declines, if less dramatic, may occur in the future.

Unlike many categories of health care expenditures, the largest proportion of payments for corrective lenses comes from patients, rather than from private or public insurance. Although a number of major collectively bargained employment contracts provide vision-care benefits, such coverage applies only to a small proportion of all workers, provides mainly for eyeglasses, and provides only partial payment for contact lenses when they are covered. In the public sector, contact lenses are insured only for therapeutic, not cosmetic, use. (In a strict sense, all contact lenses that offer vision correction or eye protection are "therapeutic" in use. However, contact lenses that provide correction or protection not achievable through the use of eyeglasses are commonly considered "therapeutic" in use while those afford-

ing benefits also attainable through the wearing of eyeglasses are considered "cosmetic," since, it is believed, the choice of contact lenses in the latter cases is made on the basis of appearance considerations.) In practice, this means that contact lenses are provided under Medicare, Medicaid, and other public programs mainly in relation to cataract or other eye surgery. As a result of this minimal role of third-party payment in the total source-of-payment pattern, insurance as a whole and public programs in particular have little discernible effect on contact lens usage, development, prices, or resource allocation patterns.

Although a large number of firms produce contact lenses, the manufacture of both soft and gas permeable lenses is concentrated among a very few large firms. However, because of many factors—e.g., the similarity of lenses within each type, the considerable substitutability and resulting competition among types, and excess capacity—competition is active in both product development and price. Where market power is most evenly distributed (hard lenses), price competition is greatest. Where large firms dominate but are surrounded by a fringe of smaller firms (soft lenses), price competition is high. Where only a few firms are in the market and one predominates (gas permeable lenses), price competition, among groups if not within this group, is at least observable.

Yet public policy has not had benign effects on market competition. As a result, the degree of competition is probably less than it otherwise would be, and the gap between the actual and potential levels may widen in the future. To the present, the history of this industry shows the important role of small firms as generators of innovational progress, service, and price rivalry. Yet the sector most open to small firms—hard lenses—is becoming less important as time passes. In the soft-lens area, energetic small firms have difficulty entering the market, and mergers and acquisitions by large firms may eliminate many of them. And small firms have the greatest difficulty in entering the fastest growing market area—gas-permeable lenses. The greatest potential obstacle to the attainment of optimal product and price competition in the future is the U.S. Food and Drug Administration's premarketing approval policies, which have been especially burdensome to smaller firms. Restrictive market approval policies may be wise for significantly new lens types, but once their effectiveness and safety become established, more flexible approaches toward minor or closely similar new developments seem warranted.

The study also examines the role of contact lens prescribers and dispensers (ophthalmologists, optometrists, and opticians) in the eye-care field. Ophthalmologists are medical doctors specializing in eye care, and vision correction is a large part of their activity. There are about 12,500 ophthalmologists in the United States, of whom 11,000 are involved in regular patient care. Optometrists, who are licensed to measure and fit corrective lenses, outnumber ophthalmologists by roughly two-to-one, and fit proportionally more corrective lenses. Opticians are usually limited to making contact lenses or to fitting them under the supervision of an optometrist or ophthalmologist, but in some States they may measure for and fit corrective lenses. There are an estimated 26,000 dispensing opticians. Recent action by the U.S. Federal Trade Commission (FTC), however, has expanded the competitive roles of these dispensing opticians. The FTC requires all lens prescribers to provide copies of the prescription to the patient. Thus, patients may take these prescriptions elsewhere, including to opticianries, for filling and fitting. State prohibitions against price competition by corrective lens dispensers are also no longer enforceable, and opticians have begun to compete on the basis of price to fill corrective lens prescriptions written by others. Large chains, with inhouse optometrists and opticians, have been the most vigorously price competitive, both for full prescribing and fitting, and for filling prescriptions brought in by patients. Accordingly, public policy has been successful in providing strong competition in the fitting of contact lenses, which is directly advantageous to patients in the forms of expanded choices and lower prices, and indirectly advantageous by exerting a strong counteracting force on any market power among lens manufacturers.

Other Federal policies—tax, import, research funding, procurement—seem to have little, if any, effect on the contact lens industry. Patent policy

is somewhat more important, but not critically so. More importantly, the procompetitive effects of enhancing competition among dispensers could be maximized subject, of course, to the maintenance of high-quality care. An assessment of the effects of unhindered mergers and premarketing approval requirements could suggest adjustments in policies that would make mergers somewhat more difficult to accomplish and market entry considerably easier. Adoption of more flexible policies of premarket approval merits particular attention.

2.
The Development of Contact Lenses

2.

The Development of Contact Lenses[1]

The oft-told history of the development of contact lenses is an interesting one, and its highlights are presented in table 1. The history usually begins with the theories of Leonardo da Vinci that a water-filled glass "half circle" could neutralize the refractive (light bending) power of the cornea and substitute the refractive power of the curved glass to improve the clarity of the image received by the retina. Leonardo suggested at least two demonstrations of his theory: 1) a water-filled glass bowl in which the person placed his or her face (presumably for brief periods) and looked through the bottom, and 2) a water-filled glass hemisphere actually worn over the eye and remarkably like a contact lens. His ideas far exceeded the ability of his times to actually implement them. However, he had correctly identified several key principles of contact lenses; neutralizing the refraction of the natural cornea by means of an artificial surface; substituting the refractive powers of a curved, clear lens in its place; and positioning that lens directly on the eye.

Almost a century and a half later, the philosopher-mathematician René Descartes suggested placing a lens at the end of a water-filled tube, the other end of which was placed on the cornea of the eye. His concept was not really practical as such tubes would require external support, but time has shown that his idea of placing the lens only over the cornea instead of including the sclera (white portion of the eye), as Leonardo had proposed, was most perceptive.

In 1801, Thomas Young, an English scientist, actually made a rudimentary set of contact lenses on the model of Descartes. Using wax, he affixed water-filled lenses to his eyes, neutralizing his own refractive power, then corrected for it with another pair of lenses. His optic device affirmed the principles formulated by both Leonardo and Descartes.

Next in the progression of the science of contact lenses was Sir John Herschel, an English

[1]Except as noted, this discussion was drawn from: Graham, 1981 (15); Lowther, 1982 (21); and Ruben, 1976 (30).

Table 1.—Summary of the Historical Development of Contact Lenses

Year	Individual(s)	Development
1508	Leonardo da Vinci	Described glass contact lens
1636	René Descartes	Tube of water used to neutralize the cornea
1801	Thomas Young	Used Descartes' principle to study the eye
1827	John Herschel	Described how a contact lens could be ground; concept of molding the eye
1887	F. A. Muller	Fitted a glass blown lens for a patient to protect the eye
1888	A. E. Fick	Described first glass lens to be worn to correct vision
1888	E. Kalt	Designed and fitted glass corneal lenses; Used ophthalmometer to fit lenses
1936	W. Feinbloom	Made lens with glass central optic and plastic surround (first plastic used in contact lens)
1938	Mullen and Obrig	First all-plastic (PMMA) contact lens
1947	N. Bier	Fenestrated minimum-clearance haptic lens
1947	K. Tuohy	All-plastic corneal lens
1950	Butterfield	Designed corneal lens to parallel the cornea; used peripheral curves
1960	Wichterle and Lim	Hydrogel polymers for contact lenses
1968		U.S. FDA became involved in regulating contact lenses
1971	Bausch & Lomb	First hydrogel lens approved in United States
1970s	J. DeCarle	Extended wear with high water content hydrogel lenses
1970s	Rynco Scientific	Use of CAB polymer for contact lenses
1970s		First clinical marketing of soft silicone lenses
1978	Danker Laboratories	U.S. FDA approval of CAB lenses
1979	Syntex Ophthalmics	U.S. FDA approval of a PMMA-silicone copolymer lens

SOURCE: G. E. Lowther, *Contact Lenses: Procedures and Techniques* (Boston, MA: Butterworths, 1982).

astronomer, who in the 1820s suggested principles for accurate lens grinding and fitting. His first contribution was to suggest grinding the inside curvature of a glass lens to conform as closely as possible to an irregularly surfaced cornea, and the outside curvature of the same lens to duplicate a normal cornea. He also proposed taking an actual mold of the eye to use in rendering an accurate interior curvature fit and using a gel-like filling for the cavity between the cornea and interior curve.

The actual making of contact lenses became possible as the necessary technological capabilities slowly emerged. The development of anesthesia in 1884 allowed for making a mold of the shape of the eye, as proposed by Herschel. Advances in optics, particularly precision glass blowing and lens grinding, made possible the accurate duplication in glass of the curvatures of the eye. Usable lenses thus were developed, but their first applications were for pathological conditions of the eye (as opposed to correcting a refraction error), since only the correction of severe problems justified the wearing of these large, heavy, and uncomfortable devices, which were tolerable only for brief periods. In Germany, F. A. Muller, a maker of artificial glass eyes, made a transparent lens in 1887 to protect a diseased eye that seems to have worked for many years.

The following year, two important developments occurred. A. E. Fick, a Swiss physician, employed a small glass bowl—more accurately, a segment of a glass sphere "bounded by concentric and parallel sphere segments"—to correct refractive errors. These appear to be the first true contact lenses, and Fick went on to design and use both corneal and scleral lenses. Concomitant advances in lens making, led by the Zeiss enterprise in Germany, made Fick's work possible and allowed for further experimentation with contact lenses in Germany, Switzerland, and France. For the most part, however, such lenses were not comfortable enough for much use in other than pathological conditions such as keratoconus, where the pressure of the lens might help suppress the conical distention of the cornea and protect it; other severe distortions of the cornea in which correction by the use of spectacles was not possible; and in cases where the cornea needed protection from infections and encrustations of the eyelids.

By the end of the 19th century, then, a plateau had been reached in the progress of contact lenses. Fairly well-fitting and carefully made glass contact lenses were available but were used on a limited scale only for occasional therapeutic purposes. Glass, even thin-blown or finely ground, is relatively heavy. Thus, small lenses would not adhere reliably to the surface of the eye, and large lenses which extended under the eyelids impeded the lubrication of the cornea and the flow of oxygen (and carbon dioxide) because they were essentially impermeable. The results of wearing these large, scleral lenses were: discomfort, irritation, swelling, and perhaps infection or other damage; the need for continuous and usually not successful artificial lubrication of the eye; and/or a cycle of short-term wearing and longer rest periods. Additionally, wearing highly fragile lenses in the eye was considerably dangerous, and the glass material itself was affected by tears. The regular use of contact lenses for simple vision correction, although nearer to reality than before, was not yet feasible. The development of contact lenses thus remained static at this point, waiting for supporting technology to catch up.

This catchup took another half-century and appeared in the form of plastics, which overcame some of the more serious limitations of glass lenses. Feinbloom, in the United States, was the first to use plastic in contact lenses. In 1936, he produced a scleral lens by bonding the glass corneal portion to an opaque, molded resin scleral band. Obrig and Mullen, also working in the United States, made the first all-plastic scleral lenses in 1938, using a new material, polymethylmethacrylate (PMMA), which was particularly easy to shape to ultra-thin dimensions and greatly superior to glass in safety, lightness, and workability. The step from plastic scleral to plastic corneal lenses was a short but difficult and important one and was accomplished by Tuohy in 1947, and the modern era of contact lenses had begun.

Tuohy and others, including Butterfield, made great progress in both the construction and design of corneal plastic contact lenses. The results

were a small, light lens of high optical quality and a design that conformed very closely to the shape of the central cornea, but with a slight "stand off" at the edges for better tear spreading for greater lubrication and oxygen delivery to the cornea. As a result, PMMA or "hard" corneal contact lenses for correcting refractive errors became commercially practical in the early 1950s, and for the next two decades, they were virtually the only type of lenses used.

The search for new lens materials and designs was partly spurred by the wide range of corrective and therapeutic requirements that one material and a few design configurations were unlikely to serve, but more so by the limitations of PMMA for routine refractive corrections. A serious limitation of PMMA is that because it is nonpermeable, oxygen-bearing tears may not be able to diffuse through the lens to reach the cornea in sufficient quantity. Without oxygen, the cornea swells and makes lens-wearing difficult. For many people, natural blinking and movement of the lens allow for an oxygen supply adequate for upwards of 16 hours of wear, so-called "daily" wear. But for many others, shorter wearing times and higher levels of discomfort can be expected, perhaps to the point of their forgoing lenses totally, especially since many wearers of contact lenses choose them over glasses essentially for cosmetic reasons.

If PMMA lenses represent the first generation of modern contact lenses, "soft" lenses, designed largely to overcome the limitations of hard PMMA lenses, represent the second generation. For the most part, soft lenses are made of hydrophilic (water-absorbing) plastic materials called "hydrogels." The basic hydrogel plastic is hydroxyethylmethacrylate (HEMA), although new hydrogel materials and other soft-lens plastics have recently been developed. These plastics absorb water (as much as 85 to 90 percent by weight) and become soft and flexible in proportion to their absorbency. In 1960, Wichterle and Lim, Czechoslovakian chemists working with Dreifus, an ophthalmologist, researched hydrogels, and with Dreifus began to formulate hydrophilic contact lenses.

Although hydrogels have become the main type of contact lenses currently on the market, they were not a practical alternative to hard lenses for a decade or more after their invention. Being soft and permeable, they were comfortable on the eye, but their water content made them difficult to handle, of poor optical quality, and raised questions about the absorption of infectious bacteria. However, within several years, improved materials and lens designs were formulated. After a few years of experimentation and improvement, Wichterle granted to National Patent Development Corp. (NPD), a U.S. firm, exclusive Western Hemisphere rights to the new hydrogel materials and to a novel molding process, now called "spin casting," for the fabrication of hydrogel contact lenses. NPD, in turn, licensed Bausch & Lomb Inc. to use these product and process patents. In 1971, after considerable improvement and careful testing, Bausch & Lomb obtained approval from the U.S. Food and Drug Administration to sell hydrogel lenses in the United States. After several years, other firms began to obtain similar approvals for their hydrogel lenses, and many firms are now in the market.

Today, there are more than 30 manufacturers of soft lenses (31,48). For any given use, different brands of lenses may differ slightly in design and hydrophilic capacity, some higher for greater comfort and permeability, others lower for greater durability and visual acuity. Soft lenses are now available for a wide variety of vision problems and for extended wear.

The decade of the 1970s thus marked the introduction, acceptance, and ultimate dominance of soft lenses over the older PMMA hard lenses, but as the decade ended a new type of lens, perhaps a third generation, was introduced. This lens is a gas-permeable hard lens, made of either cellulose acetate butyrate (CAB), PMMA-silicone combinations, or pure silicone. These lenses allow oxygen to reach the cornea through the lens as soft lenses do, while also offering the optical clarity and ease of handling of hard lenses. In 1979, the first gas-permeable hard lenses were approved for use in the United States, and recently, others have followed. Currently, in addition to the wide range of soft lenses available or being tested, experimentation with newer gas-permeable hard lenses, including extended wear lenses, is active.

The history of the development of contact lenses is considerably more detailed and complex than is suggested by a discussion of its significant developments or a chronological listing of its highlights. Today's wide range of precision-made, carefully fitted, and extensively used contact lenses represents the contributions of a large number of scientific areas and industrial sectors which played key roles. These include: physics, biology, and chemistry and their continually expanding theoretical and empirical foundations; precision glassmaking, which made possible early lenses of thin optical glass; the plastics industry, which has developed an expanded inventory of sophisticated polymer plastics that are the foundation of today's contact lenses; the precision machine tool industry, which has provided ultra-fine grinding, lathing, and molding machines for lens finishing; the optical instruments industry, for its provision of precise ophthalmic measurement and examination technology; and eye-care practitioners and technical personnel, who have utilized the new technologies and encouraged their continued evolution.

3.
Types of Contact Lenses and Their Characteristics

3.
Types of Contact Lenses and Their Characteristics[1]

The basic categories of contact lenses currently in use are the original hard (polymethylmethacrylate [PMMA]) lenses, soft hydrogels (hydroxymethylmethacrylate [HEMA] and other materials), and gas-permeable hard lenses (cellulose acetate butyrate [CAB], PMMA-silicone, and silicone). There are variations within each group, but their respective properties are similar enough to consider them as essentially the same type of lenses.

HARD PMMA LENSES

As discussed in the previous chapter, hard PMMA lenses were the first lenses introduced onto the market, and corneal PMMA lenses similar to those currently in use have been available since the early 1950s. Compared to later types of lenses, PMMA lenses can be difficult to adapt to, and perhaps as many as half of the people fitted do not become long-term wearers. Since PMMA is not water- or gas-permeable, wearers must rely on the "tear pump" action of the eye to provide oxygen to the covered portion of the cornea. As the wearer blinks, tear interchange occurs from outside the lens to beneath it, providing the necessary oxygen. Although hard lenses are very small and cover only a portion of the cornea, many persons may not be able to provide enough tears for comfortable wear. Others may "get by" for 8 to 12 hours but beyond that time, they suffer from dryness, swelling, and discomfort of the eye. Thus, hard lenses are, at best, "daily" wear lenses, but for many people they are very comfortable for that duration.

The positive characteristics of PMMA lenses are numerous. PMMA is made by annealing, a process of successive heating and cooling, which leaves it free of toxic chemicals. It thus is an inert material and safe for use in the eye. It can be molded or lathed into lenses with a high degree of precision. Once made, PMMA lenses can be reworked and modified to customize them to an individual's requirements. The result is a safe lens of excellent visual properties which very closely conforms to patient requirements. PMMA lenses require minimal use of cleaning, soaking, and wetting solutions. They may be tinted to reduce excessive light sensitivity, to make them easier to find when dropped, or for appearance reasons. They are durable, can be renewed by polishing away minor surface scratches, and often last 5 to 7 years or more. Last, they tend to be cheaper than other lens types, because they are an older product with many small suppliers and little difference among different brands.

Despite attempts to improve their permeability by drilling small holes in the lenses ("fenestration"), adding hydrogel to the PMMA, or other modifications, impermeability remains the major shortcoming of rigid PMMA lenses. Because of this impermeability, they cannot cover much of the cornea and therefore must be small. They must be light and thin to adhere to the eye, which precludes their use for correcting corneal astigmatism beyond a moderately severe degree.

In summation, then, hard lenses are effective for daily wear for those persons who have normal or better tearing action and who have mainly single vision refractive problems, such as near-

[1]This discussion of lens types and characteristics is drawn from: Aquavella and Gullapali, 1980 (3); Check, 1982 (8); *Consumer Reports*, 1980 (9); Dixon, 1982 (13); Feldman, 1981 (14); Kersley, 1980 (19); and Morrison, 1976 (27).

sightedness (myopia) and farsightedness (hypermetropia). They are not suitable for those with poor tearing action, high corneal oxygen need, difficult multifocal correction requirements, or who are unable to follow a daily regimen of care, insertion, and removal.

SOFT LENSES

Soft lenses differ from PMMA lenses in many ways. Their basic soft quality comes from their water absorbency. They are usually gas-permeable, allowing oxygen transport to the cornea. This softness and permeability make them considerably more comfortable than hard lenses, and many wearers can adapt to them almost at once. These qualities can be of great advantage to wearers, but they come at the expense of some visual clarity. Soft lenses, which may contain anywhere from 30 to 90 percent water, can be very flexible, but what is called their "bag of water" nature has an effect on refraction, yielding less clear images than provided by hard lenses. Additionally, high water content lenses are usually fragile and easily torn. Reducing the water content in order to increase acuity and durability, however, sacrifices comfort. Reducing the plastic content to increase acuity by making a thinner lens usually increases fragility. These tradeoffs are the major problem with soft lenses. Further, these lenses cannot be easily modified. The extensive, but limited, inventories of ready-made lenses and the lack of post-prescription customizing cannot possibly meet the exact needs of all wearers. Still, lenses are readily available for the most common refractory corrections and may be available for less common corrections. For most wearers the original fit is close enough, and the flexibility of the lens provides an additional, built-in element of modification.

The comfort and permeability of soft lenses allow for uses beyond the correction of nearsightedness and farsightedness. Some brands have been approved by FDA for 15-day and even 30-day extended wear. Extended-wear lenses offer particular benefits to those who find lens insertion and removal difficult, such as persons with extremely poor eyesight or troubled by arthritis or unsteadiness of the hand. Extended-wear soft lenses, therefore, are often used by persons with aphakia (i.e., those who have undergone lens removal, usually due to cataracts) who may not see well enough without contact lenses to insert them properly, and are of particular value to older persons.

The larger size of soft lenses offers another advantage. They can overlap comfortably onto the scleral portion of the eye and under the lid, which stabilizes the lenses. This allows a soft bifocal or multifocal lens to be tried in those cases of presbyopia (loss of flexibility in adjusting from far to near vision, usually associated with age) where hard PMMA bifocals have not proven successful. Multifocal soft lens are still problematical for most users, particularly as other alternatives exist, such as bifocal eyeglasses; single vision lens-eyeglass combinations; and an unmatched pair of monovision contact lenses, one correcting for nearsightedness, the other for farsightedness. The stability of soft lenses has also led to the recent introduction of soft toric lenses, which are used to correct for uneven focusing of the eye (so-called "corneal astigmatism").

Special problems associated with soft lenses relate to their hydrogel construction, fluid content, and extended-wear functions. The potential exists for the accumulation of both surface deposits and bacteria, and the latter, particularly, was thought to be a serious problem. As a result, special cleaning methods are used, and disinfection techniques are also necessary. First, "hot" methods of disinfection (e.g., boiling), and then "cold" methods (chemical solutions) were developed and appear to be equally effective in preventing serious problems that might otherwise develop in wearing waterlogged lenses for long periods of time. However, these cleaning and disinfection methods are costly, raising the expense of maintaining soft lenses to upwards of $100 a year or more and stimulating the growth of a sizable lens care products industry (31).

GAS-PERMEABLE LENSES

Gas-permeable lenses are the newest type to appear and are made of either CAB, a PMMA-silicone combination, or pure silicone. They are rigid lenses, with the optical properties of PMMA lenses, but approach soft lenses in comfort because of their permeability. They take more getting used to than soft lenses do but require considerably less care. Their rigidity helps to correct astigmatism, they are small but easy to handle, and they have recently become available in tints. Of the three types of gas-permeable lenses, the PMMA-silicone combination is the most preferred at present, but the pure silicone lens has proved popular since its introduction.

PRESENT USAGE AND FUTURE TRENDS

Both governmental and trade sources provide data on current levels and trends in contact lens use, but they are in some disagreement. Comparisons of the data in table 2, which contains estimates from the National Health Survey on corrective lens usage in 1966, 1971, and 1977, and that of table 3, which contains estimates from industry sources for the period 1970-82, show that, where the two sets overlap, the governmental statistics are considerably more conservative. For example, the National Health Survey estimates of total lens wearers in 1971 and 1977 are 2.4 million and 7.0 million persons, respectively; the trade data for 1970 and 1975 suggest that there were 8.0 million and 11.0 million lens wearers in those years. The wide gap between these two sets of estimates is explainable if the National Health Survey data relate to those who wear contact lenses, and the industry data, to those who have purchased them. In any case, caution is called for in making definitive statements about rates of sales and levels of usage of contact lenses. The subsequent analysis of trends and levels of contact lens wear derives mainly from the data in table 3, which are more detailed and current, if higher, than the data in table 2.

Table 2.—Persons Wearing Corrective Lenses: 1966, 1971, and 1977

	1966	1971	1977
	In millions		
Population 3 years and over	178.9	191.6	202.9
Wearing corrective lenses	86.0	94.3	103.3
Eyeglasses only	84.2	90.3	96.3
Contact lenses, with or without eyeglasses	1.8	2.4	7.0
	Percentages		
Percent of population wearing lenses	48.1	49.2	50.9
Eyeglasses only	47.1	47.1	47.5
Contact lenses, with or without eyeglasses	1.0	1.3	3.5

SOURCES: **1966:** U.S. Department of Health, Education, and Welfare, *Characteristics of Persons With Corrective Lenses, United States: July 1965-June 1966*, Vital and Health Statistics, series 10, No. 53, prepared by M. M. Hannaford, DHEW publication No. (PHS) 1000 (Washington, DC: U.S. Government Printing Office, June 1969). **1971 and 1977:** U.S. Department of Commerce, Bureau of the Census, *Statistical Abstract of the United States*, 1982-83 (103 ed.), Washington, DC, 1983.

The numbers of eyeglass and contact lens wearers appear to have grown at fairly steady rates since 1979, with eyeglass wearers increasing by about 5 million per year and contact lens wearers by about 1.5 million per year. Since the number of new contact lens patients per year is well above 1.5 million, it appears that substantial attrition or failure rates do occur. The stable growth rate among lens wearers, however, may be only a temporary phenomenon. Since new (as opposed to replacement) contact lenses are expensive and usually represent an alternative to eyeglasses for cosmetic reasons, it is likely that the recession of the early 1980s had a significant negative effect on lens purchases. Additionally, the sales data probably do not yet reflect the ultimate acceptance levels of recent contact lens innovations.

Perhaps the more meaningful implications of the data relate to patterns among contact lens types rather than to aggregated totals. Here, the data tell a less ambiguous story. The older hard lenses are declining in total usage, having dropped from 10 million to 7.1 million wearers between 1975 and 1982. Each year they have accounted for a declining share of both new and replacement

Table 3.—Persons Wearing Corrective Lenses: 1970, 1975, 1978-82 (trade data sources) (millions)

	1970	1975	1978	1979	1980	1981	1982 (est.)
Population requiring vision correction	100.0	107.0	112.5	118.0	125.0	131.5	138.0
Corrective lens wearers							
Eyeglasses	92.0	96.0	100.1	105.2	110.5	115.0	120.0
Contact lenses	8.0	11.0	12.4	12.8	14.5	15.0-16.5	16.3-18.0
Hard	8.0	10.0	9.0	8.0	8.0	7.8	7.1
Soft	—	1.0	3.4	4.8	6.2	6.6-8.1	8.3-10.0
Gas-permeable	—	—	—	—	0.3	0.6	0.9
New contact lens patients	—	0.9	3.3	4.5	3.0-4.4	3.2-4.6	2.8-4.3
Hard	—	—	1.7	1.8	1.2	1.0	0.5
Soft	—	0.9	1.6	2.4	1.4-2.8	1.8-3.2	1.9-3.4
Gas-permeable	—	—	—	0.3	0.4	0.4	0.4
Replacement contact lenses (pairs)[a]	—	0.3	1.6	2.1	2.2	2.5-4.1	2.7
Hard	—	—	0.9	1.0	0.8	0.7	0.4
Soft	—	0.3	0.7	1.1	1.3	1.7-3.3	2.7
Gas-permeable	—	—	—	—	0.1	0.1	0.1
Total contact lens sales (pairs)[a]	—	1.2	4.9	6.5	6.6	7.0-7.2	7.0
Hard	—	—	2.6	2.7	2.0	1.6	0.9
Soft	—	1.2	2.3	3.5	4.2	4.9-5.1	5.6
Gas-permeable	—	—	—	0.3	0.4	0.5	0.5

[a]Includes single lenses as half pairs.

SOURCES: L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983).

levels, and now represent only a small proportion, estimated at less than 15 percent, of each category. Soft lens wearers have increased substantially, particularly as the result of their dominance in the new lens market. (While soft lenses also account for most of the replacement market, a high fraction of these sales probably replace previous soft lenses, which, as noted earlier, have a short life span.) Gas-permeable lenses, the newest type on the market, exhibit a steady growth rate, accounting for 5 percent or more of all contact lenses in use, 10 to 15 percent of the lenses for new wearers, and about 10 percent of all current lens sales. Market share data for the three lens types are given in table 4.

Current trends are easily ascertained, but what of the future? That question can be addressed by dividing the actual and potential lens wearer population into four groups according to their visual correction requirements, and considering each separately in relation to the present and future characteristics of contact lenses.

Those with uncomplicated single vision problems (nearsightedness and farsightedness) comprise the first and largest of these groups. Because they represent a large share of the total market and are easy to fit with one or more types of lens, this is where the greatest market penetration has occurred, although, as was implied by the data in tables 2 and 3, the overwhelming majority within this group still rely wholly on eyeglasses. Since, on average, the total costs of contact lenses (lenses and fittings) are more than for eyeglasses, price remains an important variable in determining the rate of shift from "eyeglasses only" to contact lens use, with or without eyeglasses.

Table 4.—Share of U.S. Contact Lens Market by Lens Type, 1978-87 (est.)

	1978	1979	1980	1981	1982 (est.)	1937 (est.)
Soft lenses	49%	54%	64%	70%	75%	65-75%
Hard lenses	51	39	27	21	15	5
Gas-permeable lenses	—	6	8	9	10	20-30
Total	100%	100%	100%	100%	100%	100%

NOTE: Figures may not add due to rounding.

SOURCE: L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983).

The second and third components of the total market also are large, but the difficulties in developing wearable lenses have left most of this market untapped. These two groups are, respectively, the moderate-to-severe astigmatic, and those with presbyopia, for which bifocal or multifocal corrective lenses are usually employed.

By and large, the use of contact lenses in these three groups can be considered "cosmetic," since, with some exceptions, eyeglasses readily afford satisfactory levels of correction. For the fourth market segment, however, contact lenses can be considered therapeutic, since, using the same criterion, eyeglasses have limited capability for correction. In this group are those who suffer from corneal abnormalities such as keratoconus and other pathological conditions such as trachoma, corneal ulcers, and scarred corneas (20).

Projections for contact lens use for the short-run future can be made by extrapolating current market trends; for the medium-run future by estimating the effects of changes currently underway or impending but which have not yet materialized as strong market factors; and for the long-run future by predicting the effects of changes that today may be only hypotheses, concepts, or ideas.

In the short run, current trends are likely to continue. Contact lens wearers will increase steadily, if slowly, as a percentage of the total vision-corrected population. Soft and gas-permeable lens wearers will grow and hard lens wearers will decline as percentages of the total contact lens-wearing population. Sales of soft lenses will grow as the currently strong competition in innovation and improvement creates increasingly satisfactory products for those who have not yet adopted lenses or have failed with hard lenses. The unique qualities of soft lenses will make them increasingly attractive to those persons with visual problems not resolvable with hard or the earlier soft lenses. Accordingly, growth in the use of soft lenses is likely, perhaps at a rate of 10 to 15 percent per year as their uses for single vision problems, astigmatism, presbyopia, and therapeutic applications expand. Further, as the majority of lens wearers shifts to soft lenses, their fairly short average duration (9 to 18 months) will generate a very sizable replacement lens market.

The use of gas-permeable lenses will also grow rapidly as users of hard lenses switch over, nonusers adopt them, and those who might otherwise select soft lenses are attracted by the lower long-term costs (from less frequent replacement and simpler care procedures), and excellent vision correction of the gas-permeables. An additional attraction is that these lenses, unlike the soft ones, can be readily custom-fitted. Thus, over the next 5 years gas-permeable contact lenses will contribute substantially to the decline of hard lenses and may also take part of the market that would otherwise be won by soft lenses. Their percentage growth rate will be especially impressive, given the present small base against which that rate will be calculated.

Beyond the extension of present trends into the short-run, certain projections for the medium-run future can be made if one looks at forces of change currently in their incipiency. At present, soft lenses are fragile and not reworkable. However, promising advances in plastics and in lens manufacturing technology will result in more durable and more precisely fit soft lenses. Combined with their comfort and extended-wear capabilities, these improvements will enable soft lenses to protect their market position relative to gas-permeable lenses. As long as they remain distinguishable lens types, both soft and gas-permeable lenses will grow steadily in use. Together, they will render hard lenses obsolete, and each will find its respective market position. Soft lenses will be the product of choice for those with single vision problems who place a high premium on comfort and extended wear, and they will be especially useful for presbyopia and for conditions not correctable with eyeglasses. On the other hand, gas-permeable lenses will be attractive to the single vision problem wearer who finds them sufficiently comfortable and prefers their overall economy, ease of application, and current availability in tints.

The recent introduction of extended-wear gas-permeable lenses, however, provides a strong hint that the eventual merging of the two main types of lenses has begun and that the future will bring a new, hybrid type of lens combining the best features of both. But in the long run, many other

changes which today may only be in their basic research stages will play prominent roles, and all predictions are very uncertain. However, based on what is on the horizon today, the long-run futures of both soft and gas-permeable lenses look promising, possibly more so for soft lenses, if the distinction continues. New soft lens developments, such as optically superior, nontoxic materials requiring minimal care even in extended use, and lens-making methods that allow more exact fitting and duplication, can be expected. And as new manufacturing methods—e.g., improvements of today's low-cost spin-casting method—reduce costs, the popularity of soft lenses should increase. Accordingly, the lens of the future may well be a low-cost, easy-to-wear, visually near-perfect, extended-wear, disposable lens.

A hybrid lens that provides the best qualities of both soft and gas-permeable lenses is a distinct possibility, as mentioned. If it develops, then the terms soft and (hard) gas-permeable will be obsolete. An additional quality of the lens of the future will be durability, which may make lenses still more affordable by reducing replacement costs, and may increase their attractiveness to users by making them more interchangeable with eyeglasses, since they will be able to be handled more often without damage.

Finally, in the past, many of the important developments in contact lenses originated from a wide range of scientific and industrial sources. This lesson of the long-term past is particularly applicable to the long-term future. The technologies of electronics, imaging, optics, and all of the other sciences are expanding exponentially. In the long run, then, contact lenses will make substantial gains as a form of corrective eyewear. Given their potential development, it is at least conceivable to project their displacement of eyeglasses as the dominant method of vision correction in the not-too-distant future.

4.
Wearers, Prices, and Sources of Payment

4.
Wearers, Prices, and Sources of Payment

WEARERS OF CONTACT LENSES

"Disorders of refraction and accommodation," according to the U.S. Public Health Service, ranked 14th among the 20 most common reasons for visiting a physician but accounted for only 1.4 percent of all visits to non-Federal, office-based physicians in 1981 (52). Unlike other diagnostic categories, however, refractive examinations and corrective-lens prescribing and fitting can be obtained from eye-care professionals other than physicians (i.e., optometrists and, in some States, opticians). In fact, optometrists represent about two-thirds of those professionals legally permitted to examine eyes and prescribe corrective lenses, and they prescribe approximately three-fourths of all corrective lenses and 60 percent of all contact lenses (5,12). If all such eye care were provided by ophthalmologists, refractive disorders would rank among the top three reasons for visiting a physician, either closely following hypertension and normal pregnancy or leading them, depending on the adjustment factor chosen. Accordingly, it is not surprising that over half of the population 3 years old and above wear corrective lenses and that about 15 million persons wear contact lenses.

In table 5, data from three National Health Survey studies of corrective lens wearers are presented. These data, for 1965-66, 1971, and 1979-80, show some interesting patterns and trends among users. In each of the study periods, contact lens wearing was at least twice as prevalent among females, overall, as among males. Further, lens wearing is most common among young adults, tapering to low levels at middle age and beyond. This pattern is almost totally the opposite of the age-related frequency of use of eyeglasses. (However, in 1979-80, lens wearing in the 65 and over group, both males and females, rose sharply.) Third, over the covered period, lens wearing increased at every age level for both males and females. Thus, the general view of contact lenses as primarily a "younger female" product has substantial validity, but the pattern presently is changing in substantial ways and will be considerably different in the future. The current changes, particularly the increasing use of contact lenses by older persons, are attributable to younger lens wearers' moving through the age spectrum; the development of newer types of bifocal and toric lenses, which relate especially to the vision problems of older persons; and the

Table 5.—Contact Lens Wearers, Percent of Population, by Sex and Age, 1965-66, 1971, and 1979-80

Sex and age group	Percent of population 3 years and over wearing contact lenses		
	1965-66	1971	1979-80
Both sexes:			
All ages, 3 and over	1.0	2.1	4.5
3-16	0.3	0.6	1.0
17-24	3.7	6.6	9.4
25-44	1.3	3.0	7.7
45-54	0.4	0.7	2.1
55-64	0.3	0.7	1.6
65 and over	—	0.7	4.3
Male:			
All ages, 3 and over	0.6	1.2	2.8
3-16	—	0.3	0.6
17-24	2.0	3.4	5.3
25-44	0.9	1.8	4.4
45-54	0.3	0.5	1.4
55-64	—	0.7	1.4
65 and over	—	0.7	4.6
Female:			
All ages, 3 and over	1.3	2.9	6.2
3-16	0.4	0.9	1.5
17-24	5.2	9.5	13.3
25-44	1.7	4.2	10.7
45-54	0.5	0.9	2.7
55-64	—	0.6	1.9
65 and over	—	0.7	4.0

SOURCES: **1965-66:** U.S. Department of Health, Education, and Welfare, *Characteristics of Persons With Corrective Lenses, United States: July 1965-June 1966*, Vital and Health Statistics, series 10, No. 53, prepared by M. M. Hannaford, DHEW publication No. (PHS) 1000 (Washington, DC: U.S. Government Printing Office, June 1969). **1971:** U.S. Department of Health, Education, and Welfare, *Characteristics of Persons With Corrective Lenses, United States: 1971*, Vital and Health Statistics, series 10, No. 93, prepared by M. H. Wilder, DHEW publication no. (HRA) 75-1520, Washington, DC, 1974. **1979-80:** R. Hollander, U.S. Department of Health and Human Services, Public Health Service, Rockville, MD, personal communication, June 30, 1983.

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growth in soft and extended-wear lenses, which particularly help older persons, whose eyes are less accommodating to contact lenses than are those of younger persons. Further, differences in the rates of lens usage by women and men are narrowing, and in new fits the differences will soon be eliminated. Accordingly, the lens market will no longer be dominated by the young adult female wearer; the traditional patient base will expand widely; and all groups except perhaps children will become important users.

Although as large a part of the population with vision correction suffers from presbyopia as from single-vision problems, lens wearing is much more prevalent among the latter group. As lenses for all users improve, the greatest relative growth will be for presbyopes and astigmatics, but contact lenses will continue to be prescribed most frequently for single-vision problems. Within the single-vision category, about 60 percent have myopia, 40 percent hyperopia. In addition, the relative use of contact lenses for those with myopia runs somewhat higher than among those with hyperopia. Therefore, at least through the 1980s, the largest absolute volume of sales will continue to be for the correction of myopia, followed by hyperopia, with presbyopic use gaining quickly and perhaps passing hyperopia before the 1980s have ended.

Additional data from the National Health Expenditures Survey (51) show contact lens use to be relatively more common in suburban than rural or inner-city areas, among whites than nonwhites (particularly blacks and Hispanics), and also to be positively associated with the educational level of the family head. All of these correlations are explainable in terms of the higher income levels among suburban residents, whites, and the more educated. (Other features in the pattern of contact lens use show that lenses are more often worn by white-collar and service workers than by blue-collar or farm workers. These differences may also be explainable in part by income differentials, but probably more so by the greater proportion of women employed in the white-collar and service sectors, and perhaps also by the actual physical conditions of each type of work.) In other words, contact lenses are a "normal" economic good, with purchases expanding as income expands, or in economists' parlance, with a positive income elasticity of demand.

Data from the National Center for Health Services Research's National Health Expenditures Study (table 6) shed a bit more light on the income elasticity of demand for contact lenses. (The income elasticity of demand measures the relationship between changes in income and the resulting changes in the number of units purchased.) If we were to assume average incomes within the three classes to be $6,000, $18,000, and $30,000 respectively, with all other characteristics showing similar patterns among income classes, then the income elasticity would be approximately 0.13 to 0.27, which is a plausible range of estimation. (An income elasticity of demand of 0.13 means that a 1-percent increase [decrease] in income causes a 0.13 of 1-percent increase [decrease] in units [pairs of contact lenses] purchased.)

Although no measurement or estimation is made here of the price elasticity or cross elasticity of demand (defined as the effects on lens purchases of changes in the price of lenses and of changes in the price of other goods, particularly eyeglasses, respectively) for contact lenses, certain relationships may be suggested on the basis of recent experience. First, the demand for lenses seems to be at least somewhat sensitive to changes in the relative price of lenses in that wearers of eyeglasses frequently specify cost as one of their reasons for not switching to lenses. (Theoretically, if the demand for a product is sensitive to changes in income levels, it also is sensitive to price changes of that product. The connection between the two is the so-called "income effect" of the price change.)

Table 6.—Purchase or Repair of Contact Lenses per 1,000 Population at Different Family Income Levels, 1977

Family income	Persons with purchase or repair of contact lenses
Less than $12,000	0.9
$12,000 to $19,999	1.1
$20,000 or more	1.4

SOURCE: U.S. Department of Health and Human Services, Public Health Service, National Center for Health Statistics, *1981 Summary: National Ambulatory Medical Care Survey*, NCHS Advance data, prepared by L. Lawrence and T. McLemore, No. 88, Hyattsville, MD, Mar. 16, 1983.

Second, through time, new developments in both contact lenses and eyeglasses may have narrowed the qualitative differences between the two types of corrective lenses, leaving the remaining differences, including price, as relatively more important bases of choice than previously was the case. For example, lenses may be bought because wearers "look better" than if they were wearing eyeglasses. However, the emphasis on "fashion eyewear" has made the wearing of eyeglasses, particularly among males, considerably more acceptable. Other qualitative advantages of contact lenses may have been offset by improvements in eyeglasses: the lightness of contact lenses have been offset somewhat by the popularity of light, plastic lenses for eyeglasses; tinted contact lenses are matched by "prescription sunglasses" and photo-chromic spectacle lenses; both contact and eyeglass lenses are available in bifocal and multifocal modes; new sports goggles have eliminated the safety advantage of contact lenses in activities where spectacle frames and lenses have posed a problem; new eyeglass lenses of plastic on the inside, for safety, and glass on the outside, for durability, have just been introduced.

Thus, although the price level of corrective eyewear as a whole determines the affordability of obtaining vision correction, the price structure of corrective eyewear (the magnitude of the differential between the price of contact lenses and that of eyeglasses) appears to be influential in the choice between the two alternatives. Here again, recent events seem favorable for long-term growth in contact lens usage, because prices for lens fitting have dropped significantly and are likely to continue to compare favorably with eyeglass prices. (Causes of these price declines will be identified in the next section of this chapter.)

PRICES

In 1980, consumers spent an estimated $700 million on contact lenses, lens-care products, and professional services (23). In view of the significant growth in contact lens usage, this dollar figure would have been much higher had it not been for the notable price declines of the late 1970s, which have continued into the 1980s.

These declines are exemplified by the data in table 7, which show soft-lens list prices to the practitioner and total fitting prices, including lenses, for selected years from 1971 to 1982. Soft-lens prices fell by over 50 percent during this period. Total fitting prices have also fallen, reflecting in part the effects of the fall in the price of the lens component of the total price. Despite the high rates of general and medical price inflation during this period, which would have more than offset lens price declines, there were also strong competitive forces at work within and between the various categories of fitters which kept total prices stable or declining. Thus, contact lens and total fitting prices have experienced large reductions despite high inflation. Although price trends for gas-permeable lenses are still too early to trace, two forces running counter to each other

Table 7.—Average Soft Contact Lens List and Total Fitting Prices, per Pair, 1971-82, Selected Years

	1971-74	1975	1980	1981	1982
List price[a]	$65.00	$68.70	$50.00	$40.00	$30.00
Total fitting price:[a]					
Ophthalmologist	$500-600	$250-325	$250-300	$250-300	$250-300
Optometrist	300-350	400	250	225	225
Optical outlet	—	—	170	150-170	125
Large chain				120	100
Independent				178	160

[a]Prices are higher for extended-wear soft contact lenses.

SOURCES: L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983); and M. Carr, Health Products Research, Inc., Somerville, NJ, personal communication, July 7, 1983.

will determine that trend. First, the early dominance of Syntex in the PMMA-silicone lens field has given it an established position much like that of Bausch & Lomb in the first years of soft lenses. Without serious competition in PMMA-silicone lenses, Syntex has avoided direct price competitive moves by close rivals. (However, although Bausch & Lomb was the only seller of soft lenses for 3 or 4 years, Syntex must take heed, at least to some extent, of the prior presence of three cellulose acetate butyrate (CAB) lenses in the gas-permeable market.) On the other hand, gas-permeable lenses represent replacements for hard PMMA lenses and alternatives to soft lenses. Both of these other types of lenses have experienced sharp price reductions as the number of sellers has grown, excess production capacity has emerged, and cost-reducing production methods have been developed. In fact, wholesale hard lens prices ran less than $10 a pair in 1982 (10), and total fitting costs were, on average, 30 percent lower than for other lens types.

The prospects are strong that future price declines will be a common event in the markets, if economic forces are free to manifest themselves. While empirical verification is lacking, it may well be the case that there are no substantial economies of scale in research or manufacturing, since smaller firms show impressive records in product and process discoveries, improvements, and implementation. The economic barriers to entry are low, with capital requirements relatively modest, the necessary inputs widely available, and with few important patent barriers. And an informed group of buyers (practitioners) serve to mitigate, at least somewhat, the effects of excessive or flamboyant promotional rivalry. Accordingly, many rivals, of small but efficient size, with abundant research and production capacity, seem ready to promote technological progress, efficient production, and competitive pricing. However, there are several threats to this competitive state of affairs, particularly the regulatory barrier to entry, in the form of a costly and sometimes long approval process before widespread marketing of a lens is permitted by the Food and Drug Administration (FDA). (The matter of FDA approval is examined in ch. 7.)

SOURCES OF PAYMENT

Consideration of how the yearly $700 million expenditure for contact lenses, lens-care products, and fitting services is paid for raises two questions: first, what are the sources of payment funds, and second, does the payment pattern, specifically the share from Federal program sources, exert a feedback influence on the quantity of demand for the covered goods and services.

The three main sources of funds for health care expenditures are family out-of-pocket payment, private insurance, and government. These three sources can also be separated by the distinction between "private" and "public" sources, with family out-of-pocket and private insurance grouped together as private and government classified as public; and also by the distinction between out-of-pocket and "third-party," which includes both private insurance and government.

For all personal health care expenditures as a whole, 33 percent is paid out-of-pocket, almost 27 percent by private insurers, and 40 percent by government. Thus, the payment mix is 60 percent private/40 percent public and 33 percent out-of-pocket/67 percent third-party in origin (57).

Among the different components of personal health care the proportions vary considerably. For example, in 1981 the range, using the private/public distinction, went from 44 percent private/56 percent public for nursing home care to 96 percent private/4 percent public for dentists' services. For the out-of-pocket v. third-party distinction, the range went from 11 percent out-of-pocket/89 percent third-party for hospital care to 82 percent out-of-pocket/18 percent third-party for eyeglasses and other medical appliances. Thus, contact lenses are in a group of products with the lowest proportion of payment by third-party sources. In terms of private v. public sources, they are close to dentists' services for the lowest proportion of payments by government, with 10 percent (57).

If third parties as a whole and government in particular play relatively small roles in financing "eyeglass and appliance" purchases, those roles are even smaller in the case of contact lenses. In terms of private insurance, for example, one large survey of employer-provided health-care plans covering 21.8 million workers showed that only 3.6 million were covered for vision-care, including examinations, refractions, and eyeglass lenses and frames. When there is vision-care insurance, the study found, contact lenses may be included. Thus, private insurance for vision-care expenses applied to only 16.5 percent of the workers in this study, and coverage for contact lenses was narrower and shallower, geared mainly to the cost of eyeglasses (57).

Government programs that pay for personal health care are numerous, and include Medicare and Medicaid; the Civilian Hospital and Ambulatory Medical Program of the Uniformed Services (CHAMPUS); the Civilian Hospital and Ambulatory Medical Program of the Veterans Administration (CHAMPVA); the Veterans Administration; the military; the Indian Health Service; and other Federal, State, county, and city payers (51). All these sources together represent, as indicated, 10 percent of the payment for eyeglasses and appliances, and about 8 percent of the annual expenditures for purchases and repairs of "vision aids" (51). Little, if any, authorization exists for the provision of funds for contact lenses. Medicare, the main Federal health financing program for elderly or disabled people, pays only for lenses for therapeutic use, and most of these lenses are connected with cataract removal (4), for which intraocular lenses are increasingly being used.

Considerably less is known about the 55 separate Medicaid programs, which are jointly funded by the Federal Government and the States or territories. A review of the overall Medicaid enabling legislation makes no mention of contact lenses. Therefore, public sector outlays, while covering many millions of eligible recipients, are apparently not available for a very large majority of all contact lens purchases (4,49,54).

The result of the limited applicability of both private and public third-party arrangements is that an estimated 84 percent of all vision-aid costs are funded out-of-pocket. Of the 16 percent that is covered, more of it appears to be provided by private sources than government. Therefore, if third-party payments increase health care utilization over that occurring in a market where all payment is out-of-pocket, such effects are likely to be relatively small for contact lenses. The role of government in inducing greater demand is smaller still, since government plays a lesser role than private insurers, and that role, such as it is, is limited to a small part of the current patient population.

Further, if resources are not drawn into the development and manufacture of contact lens due to expanded utilization levels, then resource allocation to this industry has suffered relative to other medical technologies, which are more broadly covered by insurance. It is, of course, possible that developments in contact lenses would have been even more pronounced with insurance coverage comparable to that which has been available to pay for other medical technologies. Yet the performance level of the contact lens industry seems not to have been affected adversely; its record of innovation, quality improvement, and price reduction is impressive when compared to most other medical goods and services. Perhaps the explanation for this apparent paradox is to be found in the fact that, unlike other medical technologies, contact lenses are a consumer-oriented product, sold in a market setting where the buyer-seller relationships emphasize rivalry in three important dimensions: innovation, quality, and price.

5.
Producers of Contact Lenses

5. Producers of Contact Lenses

A large number of firms make contact lenses, but the overall industry is rather highly concentrated and the largest half-dozen manufacturers hold most of the market. For example, soft lenses currently make up 75 percent of total lens production, and the four largest soft lens producers account for over two-thirds of that sector, equivalent to about 55 percent of the total contact lens market (table 8). Gas-permeable lenses represent about 15 percent of the total market, but one type, PMMA-silicone lenses (which outsell the other type, CAB lenses, by four pairs to one), are almost entirely provided by one firm (table 9). Only for hard lenses, which have a small and declining share of the market, are there many sellers, no one or few of which are dominant.

Sales concentration in the predominant soft-lens sector would rank high by most economic standards. The largest firm, Bausch & Lomb, accounts for at least 40 percent of the market. The four largest (adding American Hydron, Barnes Hind/Hydrocurve, and CooperVision[1]) account for about 70 percent; and the seven largest (including UCO Optics, Wesley-Jessen, and American Optical) account for over 80 percent of the market (31). (UCO has since been acquired by CooperVision, doubling the latter's market share to approximately 15 percent and increasing the four- and eight-firm concentration levels somewhat (41).) The data on firm shares in this market segment for 1978 to 1982 are presented in table 8, which shows four- and eight-firm concentration levels to be high in each of the 5 years. However, both, especially four-firm concentration levels,

[1]CooperVision was recently sold to Nestle.

Table 8.—Market Shares and Concentration Ratios, Soft Lenses, 1978-82 (est.) (percentages)

Firm	1978	1979	1980	1981	1982 est.
Bausch & Lomb	61	48	53	48	40+
American Optical	16	19	13	11	4
Barnes-Hind/Hydrocurve	12	14	11	10	13
Wesley-Jessen	6	4	3	2	5
UCO Optics	5	8	7	8	7
Channel/Lombart	—	3	4	3	2
American Hydron	—	3	5	7	8
CooperVision	—	—	2	3	8
Vistakon	1	1	1	2	2
Other	—	—	1	7	9
Total	100	100	100	100	100
Four largest firms total	95	89	84	77	69
Eight largest firms total	100	100	98	91	89

SOURCE: L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983).

Table 9.—Market Shares and Concentration Ratios, Gas-Permeable Lenses, 1979-82 (est.) (percentages)

Firm	Trade name	Lens type	1979	1980	1981	1982 (est.)
Syntex	Polycon	PMMA-silicone	30	67	64	80
Barnes-Hind/Hydrocurve	CAB Curve	CAB	—	—	15	6
Danker Laboratories	Meso	CAB	40	20	11	6
Rynco Scientific	RX56	CAB	30	13	9	5
Dow Corning	Silcon	silicone	—	—	1	3
Four largest firms total			100[a]	100[a]	99	97

[a]Three firms accounted for the total market.

SOURCE: L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983).

have declined steadily. Although the shares of the leading firms are far from being equalized, competitors capable of eroding the share of the one-time monopolist in soft-lens manufacture, Bausch & Lomb, are well established in the market.

For gas-permeable lenses, there are fewer firms, and the dominance of the leader is greater than in the case of soft lenses. Here, as indicated earlier, the preferred PMMA-silicone lenses have 80 percent of gas-permeable lens sales. One firm, Syntex, accounts for about the entire output of PMMA-silicone lenses. (Several others were marketing this type of lens to a limited extent in 1983, but their products had not yet been approved by the Food and Drug Administration (FDA). They have been marketing their lenses under "Investigational Device Exemptions" issued by FDA and therefore must operate within certain restrictions.) Four firms produce the CAB-type, and one (Dow Corning) markets an all-silicone gas-permeable lens. Thus, the gas-permeable lens' general market is also highly concentrated, with one dominant firm, five others with small shares, and a fringe of several brands under clinical investigation or approved for a specific use only. Market share data for this sector are presented in table 9.

However, the dominance of Syntex and the almost 100 percent four-firm concentration level, while implying a potentially noncompetitive situation, must be viewed in historical perspective. The soft lens market was dominated for the first several years by the initial entrant, Bausch & Lomb, but subsequent entry, after 4 to 5 years, led to the erosion of Bausch & Lomb's share and a decreasing four-firm concentration ratio. The vigorous competition in this market has been demonstrated by the sizable price declines described in the previous chapter. Therefore, the situation in gas-permeable lenses represents, at least thus far, a replication of the development of soft lenses. If substantial entry occurs, Syntex's large share will be reduced and strong price competition will occur. But even if entry occurs only gradually, firms that may dominate in this sector of the industry must still take into account the substitutability among lens types and thus adopt prices that practitioners and patients will accept relative to those of hard and soft lenses.

For the older, hard PMMA lenses, the case is quite different. This market sector has been characterized as a "cottage industry," where small laboratories prevail. They generally operate within a small geographic area, manufacturing lenses from plastic "buttons" purchased from bulk plastics manufacturers, and providing custom services to prescribing dispensers. There are many such small manufacturers and so-called "optical laboratories" that can compete effectively with larger manufacturers. While the case is not conclusive, there is at present no evidence of economies of large-scale production in lens manufacturing of any type. However, many small manufacturers have gone out of business or suffered sales declines during the past decade because of the shrinkage of the market for hard lenses, and the small firms' inability to meet the requirements for FDA approval of the newer lens types (22). Nonetheless, this segment of the market remains especially price competitive.

In summation then, the three sectors of the contact lens industry display different degrees of competition, yet the differences are explainable in terms of the different stage in the "life cycle" of each. The mature hard lens sector has few, if any, dominant firms, and has been highly price competitive for many years. The soft-lens sector is moving out of its youth phase and now displays increasing entry, an equalizing of market power among a group of large firms, and strong competition in price and innovation. The newest product sector, gas-permeable lenses, thus far has retraced the steps of the soft-lens sector, and the economic forces at work promise to maintain that similarity, conditional on the magnitude of the barriers to entry such as those posed by premarket regulatory requirements.

With regards to the individual firms who comprise the industry, table 10 provides data on 17 major competitors, ranging from Bausch & Lomb, with 1982 worldwide lens sales of $150 million and profits of $52 million (including lens solutions), to Rynco and Alcon Optic, each with only $2 million in sales. Of these 17 firms, only Bausch & Lomb can be called a broad line optical goods producer; the others are primarily contact lens producers, although many have broad contact

Table 10.—Worldwide Sales, Profit, and R&D Data of the 17 Major Firms in the Contact Lens Industry, 1982 (millions of dollars)

Firm (and parent company)	Contact lens sales	Lens solutions sales	Operating profit
Bausch & Lomb	150.0	57.0	52
Barnes-Hind/Hydrocurve (Revlon)	38.0	48.0	8.5
CooperVision (Cooper Laboratories)	36.0	15.0	17.2
Syntex Ophthalmics (Syntex Corp.)	26.7	—	0.7
American Hydron (National Patent Development Corp.)	30.0	—	marginally profitable
UCO Optics (CooperVision)	19.0	—	2.8
Wesley-Jessen (Schering-Plough, Inc.)	15.0	—	marginally profitable
American Optical	13.0	—	loss
American Medical Optics (American Hospital Supply)	2.5	—	—
Ciba Vision Care (Ciba-Geigy)	9.0	—	loss
Vistakon (Johnson & Johnson)	8.0	—	loss
Danker Laboratories	5.0	—	loss
Dow Corning Ophthalmics (Dow Corning Corp.)	5.0	—	loss
Channel-Lombart (Channel Industries)	8.0	—	loss
Rynco Scientific	2.0	—	loss
Alcon Optic (Nestle)	2.0	26.0	NA
Allergan (SmithKline-Beckman)	—	69.0	NA

NA indicates data not available.

SOURCES: L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983); and *Moody's Industrial Manual, 1982*, vols. 1 and 2 (New York: Moody's Investor Service, 1982).

lens product lines or are owned by parent companies that range across the health care and personal products fields or even into heavy industry and broadly based conglomerate activities. In fact, 13 of the 17 largest firms are parts of larger corporate organizations as a result of mergers and acquisitions, and the acquisition of one or more contact lens firms is usually only part of a larger acquisition pattern by the parent company (see app. A).

Small firms historically have been among the industry's most successful innovators, and entry via small-firm acquisition often provides the larger acquirer with a position in the industry more advanced than it could obtain with a "de novo" entry. (For example, Syntex, which had a bifocal soft lens only "in development," recently acquired Salvatori Laboratories, a long-established, smaller firm which had moved very to close to obtaining FDA approval for a bifocal soft lens.) This advanced position, combined with the parent company's financial resources, marketing strength, and in one case a captive chain of dispensing optician outlets, provides a strong potential for eventual large-scale commercial success. Thus, on the one hand, the "deep pocket" of the acquirer, together with the innovational momentum of the acquired firm, provides an effective challenger to the market position of dominant firms, which enhances competition. On the other hand, continuous acquisitions of smaller by larger firms narrow the base of product innovation. A larger number of small, dynamic firms becomes reduced to a smaller number of larger firms, and there is as yet little, if any, evidence to indicate that their combined research productivity will exceed that of the smaller firms.

As a result of both mergers and internal expansion, almost all of the major firms produce several lines of contact lenses (see table 11). The two firms included in table 10 but not in table 11 are Alcon Optic and Allergan, each of whose primary activity is the sales of lens solutions. Most have diversified their product lines to cover all or most of the soft lenses' individual submarkets as well as gas-permeable lenses.

Thus, while the number of major competitors is growing, their full-line strategies are making it more difficult for the small, specialized firm to occupy more than a toehold position. For example, a list of FDA-approved spherical (single-

Table 11.—U.S. Product Lines and List Prices Per Lens for the 15 Major Contact Lens Manufacturers, May 1983 (except as noted)

Daily-wear soft lenses	Extended-wear soft lenses	Toric lenses	Bifocal lenses	Gas-permeable lenses
Bausch & Lomb				
Softlens/$18.00 Ultrathin U3, U4/$18.00	03, 04 (cosmetic)/$20.00[a] B & L 70 (cosmetic)/$20.00[a] CW79 (aphakic)/$40.00[a]	B & L Toric/$33.00	PA.1/$40.00	In FDA process
Barnes-Hind/Hydrocurve (Revlon, Inc.)				
Hydrocurve II (45%) 15.5-16.0 mm/$28.00 13.5-14.5 mm/$18.00	Hydrocurve (45%) (aphakic)/$49.50 Hydrocurve (55%) (aphakic, cosmetic)/$49.50	Hydrocurve Ii (45%) Daily Wear Toric/$52.00[b] Hydrocurve II (55%) Extended Wear Toric/$59.50[b]	In FDA process	GP II/$32.00[b] (CAB lens)
CooperVision (controlled by Cooper Laboratories)				
To offer daily wear O_2-T (39%) lens via licensing agreement with Ocular Science	Permalens (aphakic, cosmetic) High Plus/$55.00 Minus (therapeutic)/$40.00 Plano/$45.00 Low Plus/$40.00	In development	In development	In development
Syntex Ophthalmics (Syntex Corp.)				
CSI/$25.00	—	In development	In development	Polycon/$33.00 (Silicone/PMMA Lens)
American Hydron (National Patent Development Corp.)				
Hydron/$20.00	In development	Hydron Custom/$75.00[b] Hydron Stock/$30.00[b]	—	Hyperm lens sold in Europe
UCO Optics (CooperVision)				
Aquaflex/$22.00	—	—	—	In FDA process with Boston II lens
Wesley-Jessen (Schering-Plough, Inc.)				
Durasoft 2/$20.00 Durasoft 3/$29.50	In FDA process with Durasoft 3	Original Durasoft TT/$35.00 Durasoft 2 Toric/$39.50 Durasoft 3 Custom/$65.00	Durasoft-Tru Focal/$59.50[a]	Airlens sold in Canada; in FDA process U.S.
American Optical (M. Cunniffe and R. Wood)				
AOSoft, AOThin, Softcon } price set by distributors	Softcon (aphakic)/ price set by distributors	—	—	—
American Medical Optics (American Hospital Supply)				
Sauflon 70/$35.00	Sauflon 70 (cosmetic)/$50.00[a] Sauflon P.W. (aphakic)/$35.00[a] Sauflon P.W. (pediatric aphakic)/$60.00[a]	—	—	—

Table 11.—U.S. Product Lines and List Prices Per Lens for the 15 Major Contact Lens Manufacturers, May 1983 (except as noted)

Daily-wear soft lenses	Extended-wear soft lenses	Toric lenses	Bifocal lenses	Gas-permeable lenses
Ciba Vision Care (Ciba-Geigy Corp.)				
Cibasoft/$16.00 Cibathin/$23.00 Softint/$20.00	In FDA process with Cibathin	Torisoft/$43.00	Bi-soft/$45.00	—
Vistakon (Johnson & Johnson)				
Hydro-Marc/$20.00 Hydro-Marc Ultra Thin/$20.00 VistaMarc (58%)/$35.00 Original Durasoft/$20.00	In FDA process with Vistamarc	Hydro-Marc Toric/$45.00	—	—
Danker Laboratories				
—	Sila Rx (aphakic)/$35.00 (pediatric aphakic)/$80.00	—	Front surface bifocal/$45.00 (Gas-permeable lens)	Dura-Sil Standard/19.00 Dura-Sil Super Thin/$20.00 Meso/$22.50
Dow Corning Ophthalmics (Dow Corning Corp.)				
Gelflex/$15.00 Gelflex M-T/$15.00	Silsoft (aphakic, cosmetic)/$50.00 Silsoft Super Plus (aphakic)/$70.00	Silcon Custom/$31.00	VFL-II (Silicone)/$53.00	Silcon Stock/$20.00
Silsoft/39.50[b]	Silsight (therapeutic)/$39.50			Silcon Custom/$27.50
Channel/Lombard (Channel Industries)				
Amsof/$15.90 Amsof Thin/$15.90	—	—	—	—
Rynco Scientific				
CeluSoft/$20.50	—	—	—	RX-56/$27.50 Celuflex/$30.00

[a]Price given by manufacturer Aug. 10, 1983.
[b]Price per case.
NOTE: Since volume discounts vary by manufacturers, actual prices may differ significantly from list prices. Figures given in parentheses are the water contents on hydrogel lenses.

SOURCES: L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983); and P. Sposato, "New Ideas in Marketing," *Contact Lens Forum* 8(5):29-45, May 1983; and U.S. Department of Health and Human Services, Food and Drug Administration, National Center for Devices and Radiological Health, Division of Ophthalmic, Ear, Nose, Throat and Dental Devices, "Contact Lens Premarket Approval Application Approvals as of July 25, 1983," Silver Spring, MD, 1983.

vision correction) soft lenses (see app. A) includes those of 17 firms not included in table 11, but their combined market share is not more than 1 or 2 percent. None of the firms outside of the 15 in table 11 had an FDA approval at the end of 1983 for the sale of extended-wear, cosmetic-use soft lenses, and only two firms not on the list had an approved bifocal soft lens (31,48).

Last in this survey of the activities and relative sizes of the various lens manufacturing firms is a brief profile of each, emphasizing its method of entry into the industry and the acquisitions and licensing arrangements that have contributed to its growth. This material is presented in appendix B. These descriptions show that acquisitions, joint ventures, and licensing agreements have played important roles in firm growth and relative market shares in the contact lens industry. The public policy aspects of these growth mechanisms are discussed in chapter 7.

6.
Contact Lens Prescribers and Dispensers

6. Contact Lens Prescribers and Dispensers

Contact lenses are prescribed and fitted by three types of eye-care practitioners: ophthalmologists, optometrists, and, to a limited extent, opticians. Ophthalmologists are doctors of medicine, specializing in problems of the eye. As such, they may perform a wide variety of examination procedures and medical and surgical treatments, test for refraction errors, and prescribe and fit all types of corrective lenses. Optometrists are also specialists in eye care, but their functions, although expanding, are narrower than those of ophthalmologists. Optometrists generally measure refraction, prescribe and fit corrective lenses, and detect and diagnose vision problems and the condition of the eye for referral to ophthalmologists and other appropriate practitioners. In some States, optometrists may use drugs for diagnostic purposes, and in a few, use for therapeutic purposes also. Fewer generalizations can be made about the role of opticians, since the State laws defining their permissible scope of activities vary, but opticians are usually limited to the roles of "dispensing opticians," who make and fit corrective lenses prescribed by ophthalmologists and optometrists, either under their supervision or independently, or "optical technicians," who grind the lenses for others to fit to patients. In some States, however, opticians may also examine, prescribe, and fit patients with contact lenses, if an ophthalmologist or optometrist has already determined that the patient needs some form of corrective lenses (5,55).

OPHTHALMOLOGISTS

There are about 12,500 ophthalmologists in the United States today, of whom perhaps 11,000 are involved in regular patient care as hospital- or office-based physicians. (The remainder are ophthalmology residents or engaged in teaching and research.) Half or more of these 11,000 offer dispensing services in addition to prescribing corrective eyewear, sometimes in conjunction with opticians. They account for 30 percent of the total retail corrective lens market and about 20 percent of the contact lens market, operating from 6,000 locations with $1.35 billion in revenues (5).

Of all dispensing ophthalmologists, at present more fit soft lenses (73 percent) than hard (71 percent) or gas-permeables (51 percent). This situation is reflected in the relative amounts of the three types of lenses ophthalmologists prescribe in the aggregate, as shown by the data on prescribing practices by ophthalmologists in table 12.

Other significant data on ophthalmologists' contact lens practices relate to prices and were shown in table 7. Those data indicate that the cost of being fitted with contact lenses by an ophthal-

Table 12.—Contact Lens Fitting by Ophthalmologists, 1982

	Lens type			
	Soft	Hard	Gas-permeable	All
Percent of ophthalmologists fitting	73	71	51	—
Percent of all contact lenses fitted by ophthalmologists	68	23	9	—
Contact lenses fitted by ophthalmologists as a percent of total fittings by all practitioners	20[a]	26[a]	NA	15-20

NA indicates data not available.
[a]1979.

SOURCES: M. Carr, Health Products Research, Inc., Somerville, NJ, personal communication, July 7, 1983; S. Davidson, "Market Data Book," unpublished, Dow Corning Ophthalmics, Norfolk, VA, 1983; D. P. Hayes, "Results From the Vision Care Survey Relative to the Profile of Contact Lens Fitters," *Contact and Intraocular Lens Medical Journal* 7(1):9-10, January-March 1981; and L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983).

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mologist has decreased significantly in recent years. For example, in late 1978, the average cost of soft contact lenses from this source was $308; in 1979, it had fallen to $292, and by the end of 1982, to $262 (7,16). However, the prices paid to ophthalmologists are, on average, higher than those paid to optometrists or opticians.

OPTOMETRISTS

At present, there are approximately 22,000 practicing optometrists in the United States (out of a total of 25,000). Of these 22,000, 80 percent (about 17,500) work independently. The other 20 percent include 2,400 optometrists working for chain optical houses and about 2,000 who work for government, health maintenance organizations (HMOs), or ophthalmologists (5). Data for optometrists' prescribing practices (comparable to that for ophthalmologists in table 12) are presented in table 13.

Doctors of optometry average 12 new contact lens fittings per month (compared to 10 for ophthalmologists), and their fees generally lie between those of ophthalmologists and opticians (5,7). The cost of being fitted for contact lenses by optometrists is falling, following the general industry trend. In late 1978, for example, new soft lenses cost $285, but by 1979, the cost was down to $258, and to $218 in 1982 (7,16).

Table 13.—Contact Lens Fitting by Optometrists, 1982

	Lens type			
	Soft	Hard	Gas-permeable	All
Percent of optometrists fitting	92	91	73	—
Percent of all contact lenses fitted by optometrists	69	17	14	—
Contact lenses fitted by optometrists as a percent of total fittings by all practitioners	59[a]	62[a]	NA	60[a]

NA indicates data not available.
[a]1979 estimate.

SOURCES: I. Bennett, *State of the Optical Industry* (White Plains, NY: Advisory Enterprises, 1983); S. Davidson, "Market Data Book," unpublished, Dow Corning Ophthalmics, Norfolk, VA, 1983; D. P. Hayes, "Results From the Vision Care Survey Relative to the Profile of Contact Lens Fitters," *Contact and Intraocular Lens Medical Journal* 7(1):9-10, January-March 1981; and L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983).

OPTICIANRY: INDEPENDENT OPTICAL OUTLETS

Reliable data on opticians and their practice locations are not readily available, since only 22 States currently license opticians. The Opticians Association of America estimates that there are about 26,000 dispensing opticians in the United States (5). There has been a higher growth rate among opticians than among ophthalmologists or optometrists, reflecting their increasing roles as primary fitters and as adjuncts to the other two classes of practitioners (47).

Approximately 35 percent of dispensing opticians (as distinguished from optical laboratory technicians) are employed in so-called "independent" single shops or small (ten unit or less) chains. Another 40 percent work for optical or drug chains, and the remaining 25 percent for ophthalmologists, optometrists, or other professionals. Independent dispensing opticians account for 21.3 percent of the total retail corrective lens market (5). Table 14 presents data on contact lens pre-

Table 14.—Contact Lens Fitting by Independent Dispensing Opticians, 1982

	Lens type			
	Soft	Hard	Gas-permeable	All
Percent of independent dispensing opticians fitting	55	52	36	—
Percent of all contact lenses fitted by independent dispensing opticians	80	13	7	—
Contact lenses fitted by independent dispensing opticians as a percent of total fittings by all practitioners	20[a]	20[a]	NA	10-15

NA indicates data not available.
[a]Estimated.

SOURCES: I. Bennett, *State of the Optical Industry* (White Plains, NY: Advisory Enterprises, 1983); S. Davidson, "Market Data Book," unpublished, Dow Corning Ophthalmics, Norfolk, VA, 1983; D. P. Hayes, "Results From the Vision Care Survey Relative to the Profile of Contact Lens Fitters," *Contact and Intraocular Lens Medical Journal* 7(1):9-10, January-March 1981; and L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983).

scribing patterns by these independent dispensing opticians.

Prices paid for lenses acquired from optician outlets tend to be the lowest in the industry, with the large chains charging somewhat less than the independents and small chains. In 1981, the first year for which separate data are available, independent and small-chain opticianries charged, on average, $178 for soft lenses; in 1982, their average price was $160 (7).

OPTICIANRY: OPTICAL AND DRUG CHAINS

Data on optical and drug chains and the number of their contact lens fittings are particularly difficult to come by, and when available, are obscure or comingled with data for independent and small-chain outlets. However, the data that are known are presented in table 15, and one item is noteworthy: large chains now provide as much as 40 percent of all contact lens fittings (5). This large share is both a cause and result of the downward price trends observed for all fitters. Chain outlets offer lenses at lower prices than other sources ($100 per pair of soft lenses in 1982 [7]) and thus exert downward pressure on the entire price structure.

These effects are particularly present since 1978, when the U.S. Federal Trade Commission (FTC) overruled laws in 43 States that placed restraints on price advertisements by eye-care dispensers. This action paved the way for the great growth of chain outlets, price rivalry, and price reductions. Since low price is a key strategy of chain outlets, the FTC ruling strongly enhanced their market position. Indeed, large chains are growing larger through expansion and merger, and one lens manufacturer (Frigitronics) has built up a 400-outlet chain (Benson Optical/House of Vision). Further, in what may prove to be an especially significant innovation, several major chains, including some of the largest, are offering franchises to optometrists and opticians.

Any forthcoming FTC action in this area, particularly in regard to franchising and to the State

Table 15.—Contact Lens Fitting by Chain Outlets, 1982

	Lens type			
	Soft	Hard	Gas-permeable	All
Percent of optical chains fitting	72	71	44	—
Percent of all contact lenses fitted by optical chains	86	11	3	—
Contact lenses fitted by optical chains as a percent of total fittings by all practitioners	NA	NA	NA	30-40

NA indicates data not available.

SOURCES: I. Bennett, *State of the Optical Industry* (White Plains, NY: Advisory Enterprises, 1983); M. Carr, Health Products Research, Inc., Somerville, NJ, personal communication, July 7, 1983; S. Davidson, "Market Data Book," unpublished, Dow Corning Ophthalmics, Norfolk, VA, 1983; and L. Schwarz and D. K. Temple, *Contact Lens Industry—The Shakeout Continues* (New York: Salomon Bros., Inc., 1983).

laws that define the permissible limits of opticians in the fitting of contact lenses, will exert great influences on the extent and forms of competition among all classes of practitioners, with strong implications for future price structures and trends. Whatever happens, the large optical chain has become an important part of the contact lens distribution mechanism and promises to play a larger role in future years. In table 16, eight of the largest chains are identified, along with their present number of outlets.

In conclusion, the three classes of practitioners have become more competitive with each other, particularly since 1978, when some of the limitations on price competition and on the role of opticians as independent dispensers were reduced. As a result of these changes, the total supply of practitioner/dispensers has expanded, and the highlighting of price as a basis of choice has served as one common denominator among all types of dispensers. Increasingly, price differentials among dispensers have come to reflect their qualitative differences as perceived by consumers, regardless of whether these perceptions are borne out in fact by either actual market experience or "objective" measures of dispenser "quality." These perceived qualitative differentials seem to have narrowed over time, perhaps because soft lenses, which predominate in the market, usually have well-known company labels, and because customizing of soft lenses is not widely done. With the tangible part of the combined lens/fitting rendered more homogeneous among different types of practitioners, the remaining differences, including price, have become more important in the choice among practitioners. And with the growing influence of price, the lower prices of high-volume chain opticianries have attracted more and more consumers and pulled down the entire contact lens price structure, as described in chapter 4.

Those closest in character to the larger chains—namely, the smaller chains and independent opticianries—have been affected the most, with optometrists the next most affected, and ophthalmologists the least but still feeling the impact. If both large and small opticianries are considered together, then their emphasis on price competition most seriously affects optometrists. This expectation is supported by the decline optometrists have experienced in their soft lens market share from 60 percent in 1979 to 40 percent in 1980 (5).

Over the next several years and into the middle-run future, price competition can be expected to continue. The entire price structure for conventional contact lenses will continue to ease downward, at least relative to the structure of all prices. Within the contact lens retail price structure, positions are not likely to change, with the chain dispensers at the bottom of the structure initiating price reductions and compelling the other dispensers, mainly small opticianries and individual optometrists but even ophthalmologists, to follow. Furthermore, these competitive pressures in the retail market can be expected to spill over into the manufacturers' sector as all dispensers, led by the large chains and their expanding outlets and franchises, exert buyer pressure for lower prices in the wholesale market. Accordingly, the entire industry, wholesale and retail, promises to be characterized by a high degree of price competition along with strong rivalry in lens innovation in the years ahead.

Table 16.—Major Optical Chains and Number of Outlets, 1982

Chain owner	Chain name(s), if different from owner	Number of outlets
Searle	Pearle Vision Centers and Texas State Optical	900
Cole National	Sears; Montgomery Ward	465
Frigitronics	Benson's; House of Vision	400
Sterling		110
Lee Optical		100
D.O.C.		85
Western State Optical		64
American Vision Centers		40

SOURCE: I. Bennett, *State of the Optical Industry* (White Plains, NY: Advisory Enterprises, 1983).

THE MARKETING OF CONTACT LENSES TO DISPENSERS[1]

Manufacturers distribute their contact lenses to the three groups of dispensers, who in turn make them available to patients. Thus, manufacturers' promotional efforts are mainly directed to these professionals, although some consumer-oriented, brand-name advertising takes place.

Manufacturers offer a wide and sometimes confusing array of marketing plans, and any given firm may have several programs in effect. Further, the programs are usually in a state of change, reflecting new attempts to induce dispensers to rely more heavily on one brand or to fend off the aggressive programs of rivals. (Because of the range and diversity of marketing techniques, this discussion will focus on those of the larger firms[2] engaged in nationwide distribution, since the smaller labs depend more on reputation and word-of-mouth promotion in their local areas to promote sales.)

The larger firms often distribute lenses on a consignment basis. Some require the dispenser to pay a one-time fee per lens, others require no fee, and still others charge prescribers an annual per-lens fee on the original lens consignment. Dispensers are generally required to keep their inventories at the original consignment levels and to pay for lenses as they are ordered to restock to the specified level.

A common promotional practice is volume discounting. Manufacturers offer dispensers price cuts if they order a certain volume of lenses, and the discounts are often graduated and cumulative, linking dispensers increasingly closer to producers as their usage volume expands. At least one major manufacturer has offered prizes such as Mercedes automobiles and gold bullion to practitioners for ordering its lenses in large quantities.

Most manufacturers offer limited warranties and exchanges on their lenses. The warranties usually apply only to material and workmanship defects and exclude tearing and other damage from use and handling. The dispensers usually have 30 to 60 days to return defective lenses. They also can return those lenses not suitable for a patient; some firms give full credit, others partial credit, for such returns. Many firms now also offer lenses with no warranty, which lowers prices and reduces paperwork for dispensers. There is also a general movement in the industry to simplify and expedite warranty procedures.

Price competition and simplified billing routines are heavily used to promote sales. Prices have been dropping steadily in the industry over the past 5 years, as described in previous chapters, and between May 1982 and May 1983 only one daily wear lens was increased in price. Many manufacturers now give practitioners a choice of pricing methods: per lens or per fitting ("per case"), which allows for lens return. Both types of prices have been part of the downward price trend.

Along with rivalry in price formats and price levels, contact lens producers are also moving into "full line" marketing strategies. The goal of these strategies is to entrench a brand name across the different specialty markets, offering the dispenser "one-stop" shopping, so to speak. The competitive implications for smaller firms have not yet become clear. Full-line strategies are pursued in contact lens accessories as well as in the lenses themselves as the markets for lens solutions and practitioner aids have grown large.

To introduce prescribers and dispensers to a brand of lens, its producer may offer diagnostic lens sets free of charge or at a great discount. This technique is reported to have met considerable success with new practitioners.

Once a prescriber-dispenser begins to use a particular type of lens, firms usually emphasize service to continue the affiliation. The larger firms maintain full-time customer service and sales staffs to deal with problems. They also try to anticipate practitioners' needs and frequently use computer-generated inventory plans for individual offices. Some firms further strengthen their relationships with dispensers by training the dispensers' staffs.

[1]This discussion is drawn from Contact Lenses, 1982 (10); and various articles from the *Contact Lens Forum*, 1979-1983, provided by Patty Sposato, Associate Editor (2,18,26,32,33,35,36,37,38,39).

[2]The firms discussed include: American Hydron, American Medical Optics, American Optical, Barnes-Hind/Hydrocurve, Bausch & Lomb, Channel/Lombart, Ciba Vision Care, Dow Corning, Paris, Syntex Ophthalmics, Vistakon, Wesley-Jessen, Salvatori Ophthalmics.

Beyond the general marketing techniques described above are more unusual programs. One manufacturer (Channel/Lombart) has offered a one-time lens exchange program in which a practitioner could exchange 100 used soft or hard lenses for 100 new soft lenses at about $6 off the regular per lens price. Other firms seek goodwill through funding educational grants for student or graduate practitioners, one of a variety of ways to establish the names of firms and their products in the minds of those making selection decisions among competing products.

On a more conventional scale, some small PMMA hard lens makers are becoming distributors for the soft lenses made by larger firms, allowing the small firms to have at least some degree of participation in this much greater market and allowing the larger manufacturer to expand its distributional and promotional mechanism. Wholesale-only houses are also appearing in some regions, and at least one consortium (Product Development Consortium) of small firms has been organized to manufacture and market soft lenses.

7.
The Role of Federal Policy

7.
The Role of Federal Policy

GENERAL OVERVIEW

Federal policies affect the development, manufacture, distribution, and use of contact lenses through various paths and in varying degrees, ranging from minor to large.

Direct Federal in-house activities and external funding for vision-care research play only a slight role in the operation of the contact lens industry, one of whose main benefits to consumers lies in the cosmetic qualities of contact lenses. Similarly, tax policy may have an important effect on the industry but not in any way that is distinct from other industries. Features of the tax laws, particularly provisions for accelerated depreciation, investment credits, favorable treatment for retained corporate earnings, and restrictions on corporate divestitures favor larger corporations relative to smaller ones, but the inherent features of the contact lens industry are compatible with small firms, and their position is not seriously threatened by any advantages provided their larger rivals through these tax provisions.

Foreign trade policy does not appear to adversely affect the contact lens industry. The tariff on imported contact lenses is low, 8.5 percent of value (5.6 percent for those coming from countries with preferential treatment), much less than for almost all other components of the tariff category "optical goods," yet imports account for only a small share (7 percent in 1980) of total domestic purchases (56). (Many of the imported contact lenses, of course, may come from the foreign-owned enterprises of U.S. producers.)

Direct government procurement, an influential economic force in many other industries, is minimal for contact lenses, and Federal third-party payment mechanisms, mainly Medicare and Medicaid, pay for contact lenses only as a therapeutic item for aphakia and a few other ophthalmic conditions. This adds to the use of lenses for these conditions, and probably spurs some research and development along related lines, but has little effect on the much larger general market.

However, not all Federal policies are so easily discounted as factors influencing the contact lens industry. Three, in particular, warrant closer examination. In ascending order of impact, they are: 1) patent policy; 2) policies toward the enforcement and maintenance of competition within markets; and 3) regulatory policies that require government approval prior to the general marketing and use of products such as drugs and medical devices, including contact lenses.

PATENTS

For the most part, patents neither pose problems nor exert special influence on the contact lens industry. They seem to offer an acceptable balance between the sometimes conflicting goals of stimulating innovation and keeping market competition viable. On the one hand, they provide incentives and rewards for new product and process developments; on the other hand, they do not appear to create formidable barriers to entry. The record of innovation is a good one, covering a wide range of lens materials, many lens designs for similar applications, and a variety of manufacturing processes. Further, the majority of these developments are accessible to any lens producer. Other evidence shows that entry barriers from patents are not high: upwards of three dozen firms produce soft lenses and over 50 make hard lenses. Although relatively few firms manufacture and sell gas-permeable lenses, the market barrier in this case (and in some others) is not the unavail-

ability of materials or techniques because of patents, but premarket approval by the Food and Drug Administration (FDA), which will be examined later in this chapter.

Patents may still be important in the contact lens industry, however, because they can reserve superior materials, designs, and processes for one or a few firms to the disadvantage of others.

Among the more important patents are those deriving from Wichterle's original work on soft lenses in Czechoslovakia, for which the National Patent Development Corp. (NPD) obtained certain rights, which were then sublicensed to Bausch & Lomb. The headstart provided by the NPD patents on hydrogel material and the spin-casting method for making soft contact lenses enabled Bausch & Lomb to enter the market first (1971) and remain as the sole seller of soft lenses until 1975. The subsequent development of other hydrophilic polymer plastics allowed many rivals to get around the NPD-Wichterle product patent, and vigorous price competition has been one of the results. However, the economical spin-casting manufacturing process has continued to work to the advantage of Bausch & Lomb, enabling it to operate profitably in the face of large price declines.

However, neither of the original patents successfully blocked entry by others; the product patent was quite easy to invent around and the process patent, although very advantageous and durable, covers but one of several manufacturing methods. The resulting entry of other firms has brought lens prices down by a considerable amount since 1975, as shown in table 7 (soft lens wholesale prices were $68.70 in 1975, but only $30 in 1982). Accordingly, patents seem to be a rather noncontroversial element in the contact lens industry. However, to remain so, they should continue to be carefully defined, affording only the reasonable minimum degree of exclusivity warranted by the particular discovery or invention.

THE MAINTENANCE OF MARKET COMPETITION

Policies to protect competition in the markets of the U.S. economy are administered at the Federal level by the Department of Justice and the Federal Trade Commission (FTC). The two agencies enforce the Federal antimonopoly laws and in other ways also seek to maintain, restore, or create competition in society's interest.

Two facets of the contact lens industry's activities relate to these laws and enforcement agencies. The first of these is the considerable merger activity that has occurred up to the present time, including the acquisition of smaller firms by larger ones within the industry, and of larger firms by external industrial corporations. Under the Clayton Act, mergers that may substantially lessen competition are prohibited, and thus an examination of these mergers in the context of the Clayton Act is instructive.

The second link between the contact lens industry and the antitrust enforcement agencies is found in the distributional mechanism by which lenses reach the consumer, particularly the presence or absence of competition, and the forms it takes, among dispensers. In recent years the FTC has addressed two restraints on distributional competition: State limitations on the competitive opportunities for opticians, and State approval of professional prohibitions on price competition by lens prescribers and fitters.

Mergers

Many of the numerous mergers that have occurred in the contact lens industry are identified in appendix B. Since none of these involved the acquisition of one major producer by another (generally illegal under the Clayton Act), the observed degrees of market concentration, if somewhat higher than had these mergers not occurred, are mostly explainable in other terms, mainly the early phases of the typical industry life cycle.

But concentration levels are not the only basis for judging the effect of mergers. The absorption

of smaller firms by larger ones threatens a major source of innovation. The history of the industry is replete with the achievements of individual scientists and small firms. For example, key contributions in the development of the soft lens sector include those of the then-small NPD in the origination of the product, and the later research contributions of such smaller firms as Milton-Roy (since acquired by Bausch & Lomb), Calcon Laboratories, Polymer Optics, Salvatori Ophthalmics (these last two recently have been acquired by Syntex), Rynco Scientific, Danker Laboratories, and others, none of which rank among the major firms.

State Commercial Practice Restraints

Regulation of the commercial practices of eye-care professionals occurs at the State level and has an especially strong impact on the prices consumers ultimately pay for their contact lenses.

The acquisition cost of contact lenses includes, in addition to the lenses, a refraction test and lens prescription, post-refraction corneal measurement, trial lens fitting, and followup examinations and care. Competition among lens manufacturers has brought the price of lenses down substantially, but lens prices are not the major component of the total cost of obtaining contact lenses, at least from ophthalmologists and optometrists. The predominant component is the professional services required to examine the eye and to choose and fit the lenses with satisfactory results. Thus the potential gains from competition, including price, in these services considerably outweigh those from competition among lens manufacturers. In fact, competition in the service component of contact lens acquisition costs has been the main contributor to the price declines observed for all major lens types.

State laws covering eye-care professionals vary from one class of practitioner to another, and vary sharply from State to State for optometrists and opticians. Ophthalmologists, as medical specialists, are governed by medical practices acts, which are essentially uniform from State to State. Optometrists and opticians, however, are subject to other specific regulations such as those issued by State optometry boards. Generally, the regulations on these two classes of practitioners cover professional qualifications for licensure; restrictions on employment activities and optometric and optician outlet locations, including branching; and limitations on doing business under a trade name. Optometrists are usually more restricted than ophthalmologists and less restricted than opticians in their provision of eye-care services (55).

The greatest State-to-State variation in permissible activities is in the case of opticians. These variations, shown as they relate to the provision of contact lenses, are given in table 17. In no State can opticians prescribe corrective lenses. In the five States comprising group I, they are "expressly

Table 17.—Contact Lens Fitting by Opticians: Survey of State Limitations (including District of Columbia)

I.	States where opticians are expressly permitted to fit contact lenses:	
	Arizona	North Carolina
	Connecticut	Ohio
	Massachusetts	
II.	States where opticians are expressly forbidden to fit contact lenses:	
	Kansas	New Mexico
	Missouri	Vermont
	New Jersey	
III.	States where opticians may fit contact lenses on the direction of or under the supervision of an ophthalmologist or optometrist:	
	Alaska	Mississippi
	California	Nevada
	Colorado	New York
	Delaware	Oregon
	Florida	South Carolina
	Hawaii	Tennessee
	Illinois	Texas
	Kentucky	Virginia
IV.	States where opticians may dispense contact lenses on a fully written prescription:	
	Alabama	Florida
	District of Columbia	Wyoming
V.	States where law on the question is ambiguous or nonexistent:	
	Arkansas	Nebraska
	Georgia	New Hampshire
	Idaho	North Dakota
	Indiana	Oklahoma
	Iowa	Pennsylvania
	Louisiana	Rhode Island
	Maine	South Dakota
	Maryland	Utah
	Michigan	Washington
	Minnesota	West Virginia
	Montana	Wisconsin

SOURCE: U.S. Federal Trade Commission, Bureau of Consumer Protection, *State Restrictions on Vision Care Providers: The Effects on Consumers ("Eyeglasses II")*, Washington, DC, 1980.

permitted" to do post-prescription corneal measurements, select appropriate lenses, and complete the fitting procedure. In the five States in group II, they are expressly forbidden to perform any of these procedures. In the 16 States in group III, they may perform the post-prescription procedures "on the direction or under the supervision" of a prescribing ophthalmologist or optometrist. The four jurisdictions in group IV permit opticians to select and fit lenses for a patient with a "fully written" prescription (containing both refraction test information and post-refractive eye measurements) from an optometrist or ophthalmologist, and in the 22 States in group V the law is "ambiguous or nonexistent."

An analysis of restrictions on opticians' activities raises the question of the extent to which they are warranted as consumer protections and the extent to which they are intended to constrain the competition posed by opticians against ophthalmologists and optometrists. The FTC has examined these questions and has come to view many of the restraints to be both unnecessary in terms of protecting the consumer and undesirable from a competitive point of view. (These conclusions have been strongly challenged by both ophthalmologic and optometric professional groups.) Accordingly, in the proposed "Eyeglasses II rule," the FTC staff recommended making contact lens fitting by opticians more accessible to consumers. The FTC staff did not suggest that a broad Federal law supplant the individual State laws (although Federal law can do so) so the effects of the proposed rule would occur only in States where opticians can fit or dispense contact lenses. The ruling would require the initial examiner (ophthalmologist or optometrist), initial fitter (ophthalmologist, optometrist, or optician) and any subsequent fitter to provide patients with complete and fillable copies of their contact lens prescriptions so they could have the original or subsequent lenses fit by opticians, if they so choose and where the State law allows. At the end of 1983, this proposal was "on hold," awaiting the FTC's decision whether or not to take action. It may not be adopted, it may be adopted as is, or it may be adopted in expanded form (29).

Although not suggested by FTC staff, the FTC ruling could supersede all State laws, widely broadening the rules on opticians' practices to make them fully competitive with optometrists and more so with ophthalmologists. This type of action could increase competition in the marketplace while allowing for due assurance of quality. The less sweeping Eyeglass II rule would achieve these results in lesser degree.

Last, the FTC has been a participant in a successful attempt to expand competition—specifically, price competition—in the fitting of contact lenses. State laws directly or indirectly prohibiting price advertising by professionals have been severely narrowed on two grounds. First, limitations and sanctions imposed by professional groups against price advertisers invite challenge under the antitrust laws as price-fixing agreements. Second, this type of restriction on advertising and direct statutory prohibitions is of doubtful enforceability because of their apparent conflict with the rights of free speech granted by the first amendment to the Constitution. The Supreme Court has ruled that truthful advertising falls within these rights (3a, 39). Accordingly, price advertising by optical outlets has become common and has generated an increased awareness of prices by consumers. As a result, optical outlets have priced their services at the lower end of the price range and have pulled down prices charged by other contact lens providers. Among outlets, the large optical chain has been an especially vigorous price competitor, providing soft lens fittings for an average price close to $100. Thus, Federal policy, through the FTC, has contributed to price competition among lens care providers and has the potential, through the presently shelved Eyeglasses II rule, to create more market alternatives and further price competition, possibly in every State.

FDA REGULATORY POLICY

Of all the aspects of Federal policy that bear on the operation of the contact lens industry, none is more controversial or perhaps as influential as the requirement that soft and gas-permeable lenses be approved by the FDA for safety and efficacy prior to general marketing. Such a requirement generates both benefits and costs for society. The benefits stem from the greater knowledge and experience acquired in the preapproval laboratory and clinical studies, which may lead to more effective and safe products and their wiser use. The costs are broader in variety, including the resources expended in any preapproval studies that otherwise might not be conducted, the impacts on consumers from delayed or denied approval of new contact lenses, and any anticompetitive impacts of the regulatory barrier. Ideally, premarketing approval would impose only those costs that are outweighed by the resulting benefits, but for soft and gas-permeable lenses this may not be the case. Controversy exists because the regulatory process places a high benefit on problems averted by cautious premarket testing. Producers, on the other hand, since they bear much of the costs directly, are especially sensitive to this side of the equation relative to the benefits. Accordingly, it may be inevitable that regulators and the regulated, with different perceptions of the weights to give benefits and costs, are in conflict over the appropriate extent of regulation. In the case of contact lenses, FDA's policies have remained unchanged, due largely to the complexity of the law in effecting a lower level of regulation, and, to a lesser extent, the opposition of some firms that have gained marketing approval for their products under the current high standards.

The Origins, Development, and Scope of FDA Authority Over Contact Lenses

An understanding of the economic effects and current issues in the regulation of contact lenses requires an understanding of the law itself, including a look at its origins and present features.

Prior to 1968, when only hard contact lenses were available, there was little, if any, regulation. However, in 1968, formal regulation of contact lenses began as a result of two factors. These were the development of hydrophilic soft lens material, and two court cases (1,42) that established FDA's authority to regulate contact lenses, nylon sutures, and several other "devices" as drugs, and to subject them to premarket approval requirements comparable to those for new drugs. A medical devices group was set up to handle this responsibility, and some guidelines for contact lenses were established in 1969. (The first approval under these guidelines for soft lenses was granted to Bausch & Lomb in 1971.) In the 1976 Medical Devices Amendments to the Federal Food, Drug, and Cosmetic Act, contact lenses were specifically defined as medical devices.

The 1976 law established three classes for all medical devices according to the degrees of risk associated with their uses. Class I devices are not used for sustaining human life and do not pose significant risks to human health. Devices so classified must be made in accordance with good manufacturing practices (GMPs), which include keeping a device master file that contains design specifications, production and quality assurance data, control numbers and dates of manufacture, distribution information, and complaint records.

Devices placed in Class II are (somewhat unclearly) defined as those for which the "general controls" of Class I offer insufficient assurance of safety and effectiveness, and information exists for establishing "performance standards." Class II devices must meet the Class I standard of good manufacturing practices, as well as the Class II performance standards; but no Class II performance standards have been formulated, so Class II devices are, in effect, treated as Class I devices.

Class III was established for those devices for which Class I controls offer inadequate protection, Class II performance standards do not exist due to the absence of sufficient information, and the device "supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury." All medical devices produced after 1976 that are not "substantially equivalent" in intended use, safety, and effectiveness to de-

vices marketed prior to 1976 are automatically placed in Class III and require FDA "premarket approval" prior to their general distribution and use, unless they are reclassified to a lower class. They must also meet the general controls requirements for Class I and Class II devices.

Contact lenses were originally placed in Class III, except for hard (PMMA) lenses, which were placed in Class II. At the end of 1983, all lenses with 95 percent or more PMMA were in Class II (6), and the FDA was engaged in a lengthy procedure to reclassify daily-wear spherical soft lenses and rigid gas-permeable lenses to Class I (or perhaps Class II). The reclassification of rigid gas-permeable lenses was denied by FDA in December 1983 because of inadequate, publicly available data on safety and effectiveness (43).

The route for obtaining premarket approval for new Class III devices is the Investigational Device Exemption (IDE) process, which allows a producer to market a device on a limited scale, under controlled conditions, to obtain the information necessary for FDA evaluation. IDE guidelines are established by the FDA, and the study protocols set forth by manufacturer must conform to these guidelines.

Typically, only the large contact lens manufacturers have performed full IDE studies from testing the effects of the polymer on corneal tissue all the way through the actual clinical trials of the finished lenses (28). Studies of this scope usually cost $1 million or more (40). Smaller makers of contact lenses, who usually purchase the polymer "buttons" from another source, leave tissue testing and other related studies to the polymer manufacturer and just sponsor the clinical trials. These trials usually take from 6 to 12 months and cost between $250,000 and $350,000 (28,40).

The Effects of the Present System of Regulation

Regulation has had several effects on the structures of contact lens markets, and the higher classification for soft and gas-permeable lenses has created larger effects on them than on hard lenses. The negligible regulation of hard lens market entry before 1969 and the modest regulation since then have kept the barriers to entry low, explaining in large part why this industry sector is characterized by many firms, mostly small, competing in price, innovation, and service, usually on a local basis.

In contrast, Class III status for other lens types poses a formidable financial barrier for the small firm; as a result, few of them have gained a position in these markets, although a small number have managed to come into specialized sectors. Thus, the soft and gas-permeable lens markets are almost wholly accounted for by large firms, many in the case of soft lenses, only a few in the case of gas-permeable lenses. As both sectors grow relative to hard lenses, the smaller firm may become less prominent in this industry. The number of small producers has declined sharply, and most of the survivors have had to steadily reduce their output and employment levels (22,28).

Paradoxically, regulation also offers a temporary method of survival, which many have grasped. Since their survival depends on being able to market the newer, more popular lens types, but premarket approval is costly, many smaller firms have capitalized on the letter, if not the spirit, of the IDE. They have begun to produce and distribute lenses for supposed "clinical investigation" purposes, but really to gain a toehold in these otherwise foreclosed markets. Since IDEs initially required that clinical investigations contain a minimum level of case studies but specified no ceiling, they provided much more than a modest level of opportunity. But even large sales under an IDE may not be profitable if full case files and reporting systems are maintained, thus creating an incentive, even the necessity, for such costly work to be foregone. The hope of many of these firms seems to have been to market their lenses as investigatory products extensively and indefinitely, with little accountability to the FDA as to results, or that reclassification of soft and gas-permeable lenses would render the whole IDE procedure moot before the time of accountability arrived.

Recent action by the FDA, however, may well close this marketing of lenses. Open-ended investigational periods and data collection can now be halted by mandatory FDA cutoff dates for

these IDEs and other new criteria that firms must follow. In the absence of reclassification, this cutoff policy may render the small firm a minimal factor in the new product markets.

The complex question of reclassification raises two important points. First, standard, proven materials, such as the HEMA polymer used for soft lenses, might be reclassified to Class II or I, while newer materials could remain in Class III. In other words, reclassification could be ongoing and determined more by actual risk and less by possible risk, as time passes, than is presently the case. Reclassification could rely heavily on general experience-in-use of lens materials and types as they become more commonly adopted and thereby become stronger candidates for reclassification.

Second, the professional literature and reporting of problems from lens use is also a contributor to the diminishing role of small firms. Unlike the case of drugs, for which a large body of independent clinical literature is generated by professional sources and can be called on to support premarket approval applications by small market entrants, almost all clinical studies of contact lenses are made by the larger manufacturers and, thus, are proprietary information not to be used by other producers in support of their applications without permission. In addition to the redundancy of effort caused by the absence of a common base of available clinical documentation, this "ground zero" approach rewards early entry and creates for those who clear the premarket approval hurdle a vested interest in keeping the barrier high for other would-be entrants. Accordingly, independent professional clinical studies of new lens materials, designs, and uses could be encouraged. (Although funding these studies poses a practical problem, it is not an insurmountable one. One possibility is an excise tax on lenses, earmarked specifically for clinical research purposes.)

The likely structural effects of the Class III premarket approval requirement in the contact lens field are fewer firms entering at a slower rate. Any entrant will be delayed; many, particularly small firms, may not be able to enter at all. In turn, any effects on structure are likely to be translated into changes in market behavior. Competition among fewer firms often differs from that among many, and competition among large firms takes different forms than that among smaller firms. Consequently, although price competition may be seen in the market for soft and gas-permeable lenses, it may well be less than would occur if smaller firms were also in these markets. The emphasis in rivalry threatens to shift increasingly to promotion and away from price. Vertical ties between manufacturers, prescribers, and outlets are more likely to emerge, narrowing product choice to consumers.

Smaller firms may continue to find ways to survive and to create some market competition, although in narrower roles than the protection of maximum competition calls for. Operating as licensees of other firms, especially those ranking below the leaders in market share, smaller firms can increase the challenge against the dominant firms. By acting in consortia, small firms may even generate a research effort. But neither their price nor research roles are likely to approach the magnitudes that small firms have achieved in the hard lens market and in certain specialty areas of the soft lens market (28,34).

Thus, the likely economic effects of FDA regulatory policy toward contact lenses are not the elimination of competition or serious threats of its large-scale curtailment, but a degree of limitation. What is at stake is the rigor of market competition. Consumers of contact lenses may be less well off if small firms, which history shows to be especially vigorous competitors in contact lens development and pricing, are constrained, because of limited economic resources, from entering the market as effective rivals.

In conclusion, the study of regulatory and other Federal policies toward contact lenses, their manufacturers, dispensers, and users, is instructive both for what it tells us about the effects of these policies on the economic performance of the contact lens industry, and for the broader implications offered about regulation in general. Either way, the objective is wiser and more effective Federal policy determination and administration.

Appendixes

Appendix A.—FDA Approved Contact Lenses and Current Prices

Company & (Parent)	Lens	Price per case	Per lens
Daily-wear soft lenses:			
Advanced Soft Optics	Softics	24.00	17.00
Alcon Optics (Nestle)	Tresoft	—	15.95
American Hydron (National Patent Development Corp.)	Hydron	30.00	20.00
	Zero 4 Ultra-Thin	30.00	18.00
American Medical Optics (American Hospital Supply)	Sauflon 70	—	35.00
American Optical (M. Cunniffe & R. Wood)	AOSoft	Prices set by distributors	
	AOThin	Prices set by distributors	
	Softcon	Prices set by distributors	
Barnes-Hind/Hydrocurve (Revlon, Inc.)	Hydrocurve II, 45%:		
	15.5/16.0 mm	38.00	28.00
	13.5/14.5 mm	38.00	18.00
	Hydrocurve, 55%:		
	14.0, 14.5 mm	—	49.50
Baurs & Krey	Weicon	Price information not available	
Bausch & Lomb, Inc.	Soflens	30.00	18.00
	U3,U4 (thin)	30.00	18.00
Briggs Ophthalmics	Hydracon 55%	—	20.00
Channel/Lombart (Channel Industries)	Amsof	23.00	15.90
	Amsof thin	23.00	15.90
Ciba Vision Care (Ciba Geigy Corp.)	Cibasoft	—	16.00
	Cibathin	—	23.00
	Softint	—	20.00
Coast Contact Lens, Inc.	Hydracon 55%	—	20.00
Contact Lens Corp. of America	Softact	—	12.00
	Softact II	Price information not available	
Custom Contact Lens Labs	Custom-Flex	22.50	12.95
Dow Corning Ophthalmics (Dow Corning Corp.)	Gelflex	—	15.00
	Gelflex M-T	—	15.00
	Silsoft	39.50	—
Flexlens	Flexlens	—	37.50
Kontur Kontact Lens Co., Inc.	Hydracon 55%	—	20.00
Metro Optics	Metrosoft II	24.50	15.50
	Metrosoft M Series (thin)	24.50	15.50
Omega Optical	Omega Soft	—	25.00
	Omega Soft & Thin	—	27.20
	Omega D & DT	—	17.00
Optech, Inc.	Fre-Flex	—	30.00
Paris Softsite Lens Co.	Softsite	—	18.50
PDC Corp.	PDC	—	19.95
Rynco Scientific	CeluSoft	—	20.50
Salvatori Ophthalmics (Syntex Ophthalmics)	Sof-Form II	—	19.95
Strieter Laboratories	Accugel	26.00	16.00
	Accugel Thin	26.00	16.00
Syntex Ophthalmics (Snytex Corp.)	CSI	—	25.00
UCO Optics (CooperVision)	Aquaflex	28.00	22.00
Vent-Air Optics	Nu-Soft	50.00	50.00
Vision-Ease Contact Lens Co. (Buckbee-Mears Co.)	Aqua Soft	—	17.00
Vistakon (Johnson & Johnson)	Hydro-Marc	—	20.00
	Hydro-Marc Ultra Thins	—	20.00
	Vistamarc 58%	—	35.00
	Original Durasoft	—	20.00
Wesley-Jessen (Schering-Plough, Inc.)	Durasoft 2	—	20.00
	Durasoft 3	—	29.50

Company & (Parent)	Lens	Price per case	Per lens
Extended-wear soft lenses:			
American Medical Optics	Sauflon P.W. (aphakia)	—	*50.00
	Sauflon 70 (cosmetic use)	—	*35.00
	Sauflon P.W. (pediatric aphakia)	—	*60.00
American Optical	Softcon (aphakia)	Prices set by distributors	
Barnes-Hind/Hydrocurve	Hydrocurve 45% (aphakia)	—	49.50
	Hydrocurve 55% (aphakia and cosmetic use)	—	49.50
Bausch & Lomb, Inc.	O3,O4 (cosmetic use)	—	*20.00
	OW79 (aphakia)	—	*40.00
	B & L 70 (cosmetic use)	—	*20.00
CooperVision	Permalens (aphakia, cosmetic use):		
	High Plus	—	55.00
	Minus (therapeutic)	—	40.00
	Plano	—	45.00
	Low Plus	—	40.00
Danker Laboratories	SilaRx (aphakia)	45.00	35.00
	(pediatric aphakia)	100.00	80.00
Dow Corning	Silsoft (aphakia, cosmetic)	70.00	50.00
	Silsoft Super Plus (aphakia)	90.00	70.00
	Silsight	50.00	39.50
Paris Softsite	Softsite (therapeutic)		
	Minus (therapeutic)	—	22.00
	Plus (therapeutic)	—	23.00
	Aphakic (therapeutic)	—	35.00
	Plano (therapeutic)	—	29.00
Toric soft lenses:			
American Hydron	Hydron (Custom)	75.00	—
	Hydron (Stock)	30.00	—
Barnes-Hind/Hydrocurve	Hydrocure II Daily Wear Toric—45%	52.00	—
	Hydrocure II Extended Wear Toric—55%	59.50	—
Bausch & Lomb, Inc.	B&L Toric	—	33.00
Ciba Vision Care	Torisoft	—	43.00
Optech, Inc.	Fre-Flex Custom Toric	—	**75.00
Salvatori Ophthalmics	Bal-Flange Toric	—	40.00
Vistakon	Hydro-Marc Toric	—	45.00
Wesley-Jessen	Original DuraSoft TT	—	35.00
	DuraSoft 2 Toric	—	39.50
	DuraSoft 2 Custom Toric	—	65.00
Bifocal soft lenses:			
Bausch & Lomb, Inc.	P.A. 1	—	40.00
Ciba Vision Care	Bi-Soft	—	45.00
Wesley-Jessen	Durasoft-Tru Focal	—	*59.50
Gas-permeable lenses:			
Barnes-Hind Hydrocurve	GP II	32.00	—
Danker Laboratories	Dura-Sil Standard	29.00	19.00
	Dura-Sil Super Thin	30.00	20.00
	Front Surface Bifocal	55.00	45.00
	Meso	32.50	22.50
Dow Corning	Silcon Inventory	28.00	20.00
	Silcon Custom	33.00	27.50
Rynco Scientific	RX-56	—	27.50
	Celuflex	—	30.00
Syntex Ophthalmics	Polycon	—	33.00

*Prices provided by the firms Aug. 10, 1983.
**"Suggested distributors' price.

SOURCE: P. Sposato, "The 'Bosses' Behind the Private Eyes," *Contact Lens Forum* 8(4):35-55, April 1983; and U.S. Department of Health and Human Services, Food and Drug Administration, National Center for Devices and Radiological Health, Division of Ophthalmic, Ear, Nose, Throat and Dental Devices, "Contact Lens Premarket Approval Application Approvals as of July 25, 1983, Silver Spring, MD, 1983.

Appendix B.—Major Contact Lens Manufacturers, Methods of Entry, and Acquisitions and License Agreements[1]

Bausch & Lomb

Method of entry: Entered de novo in daily-wear soft lenses in 1971, using exclusive licenses obtained from National Patent Development Corp. (NPD) in 1966 to produce and sell soft lenses made of basic hydrophilic polymer developed in Czechoslovakia and to use spin-casting production method also developed in Czechoslovakia.

Acquisitions: Bausch & Lomb acquired design for toric soft lenses from *Milton Roy Co.* when that firm went out of business in 1979 and sold its manufacturing facilities to Bausch & Lomb. Recently acquired worldwide rights to two soft lens tinting processes from *Leroy Meshel, M.D.*, of California. In October 1933 Bausch & Lomb acquired *Polymer Technology Corp.*, a maker of gas-permeable lens material and lens care solutions.

Revlon (Barnes-Hind/Hydrocurve)

Method of entry: Acquired number three firm in contact lens industry, *Continuous Curve*, in August 1980.

Other acquisitions: Acquired *Coburn Optical Industries* (1975), maker of plastic and glass eyeglass lenses and interocular lenses. In 1976 acquired *Barnes-Hind Pharmaceuticals*, major producer of lens care products. Continuous Curve and Barnes-Hind operations combined to form Barnes-Hind/ Hydrocurve. Revlon has been licensed by National Patent Development Corp. (NPD) to manufacture and sell soft lenses, after NPD's successful suit for patent infringement in 1982.

CooperVision (controlled by Cooper Laboratories)

Method of entry: Entered de novo. Created from formerly wholly owned subsidiary of Cooper Labs in 1980.

Acquisitions: In June 1983, acquired *UCO Optics* from Union Corp., giving CooperVision 15 percent of overall soft lens market and number two position in industry. Before acquisition CooperVision had 8 percent of market and was tied for number four position with American Hydron; UCO Optics had 7 percent and was ranked number five. In 1980, acquired *Smith, Miller & Patch* and *Flow Pharmaceuticals* from Cooper Labs; also acquired *Global Vision*, a soft lens maker, from Cooper Labs. In 1981, bought *C.V. Labs Ltd.*, a British lens manufacturer, and *International Lens Corp.*, which holds patents on cast molding lens manufacturing process.

Syntex Corp. (Syntex Ophthalmics)

Method of entry: Acquired *Polymer Optics*, maker of the polycon gas-permeable lens, in 1977.

Acquisitions: In November 1978 acquired *Corneal Sciences, Inc.*, maker of soft lenses. In May 1983 acquired *Salvatori Ophthalmics*, maker of soft lenses, obtaining a daily wear lens, and extended wear and bifocal lenses then in FDA approval process. Prior to this acquisition, Syntex had daily wear and gas-permeable lenses only, and was developing toric and bifocal lenses.

National Patent Development Corp. (American Hydron)

Method of entry: Entered de novo. Company formed by NPD in 1978.

Acquisitions: Acquired original patents for soft lens hydrophilic polymer and spin-casting production method from Czechoslovakian Academy of Science in 1964. Sublicensed Bausch & Lomb to manufacture soft lenses by spin-cast method. Has reacquired some rights to make soft lenses via spin-casting, and some rights to the cast molding process through partial acquisition of *International Lens Corp.* stock in 1973. International Lens subsequently bought by CooperVision. American Hydron has entered *joint ventures* with French, Japanese, Canadian, and English firms to market products in those countries. As a result of successful infringement suits, NPD receives an 8 percent royalty on lens sales from Revlon, Johnson & Johnson (Vistakon), Ciba-Geigy, Nestle (Alcon), Channel-Lombart, Schering-Plough (Wesley-Jessen), and American Optical. Also has a *joint venture* (1983) with *American Hospital Supply* (American Medical Optics) to develop extended-wear soft lens.

Schering-Plough (Wesley-Jessen)

Method of entry: Acquired *Wesley-Jessen* in 1980, number seven in industry at that time.

Other acquisitions: None.

[1]Parent company is listed first and acquired companies are in italics.

American Hospital Supply (American Medical Optics)

Method of entry: Acquired Heyer-Schulte in 1974. Created American Medical Optics around contact lens technology acquired from Heyer-Schulte.

Other acquisitions: Sauflon International in 1978. *Joint venture* with *NPD* in 1983 to develop extended wear lens. Majority of current sales are to Bausch & Lomb, which markets American Medical Optics' extended-wear lens for aphakic and cosmetic use.

Ciba-Geigy Corp. (Ciba Vision Care)

Method of entry: Formed *joint venture* with *Titmus-Eurocon* (West Germany), Europe's largest maker of contact lenses, to sell Titmus-Eurocon products in the United States (1980). In 1983, Ciba-Geigy Corp. purchased *Titmus-Eurocon.*

Other acquisitions: None.

Johnson & Johnson (Vistakon)

Method of entry: Acquired *Frontier Contact Lenses* (now Vistakon) in 1981. Frontier Contact Lenses ranked ninth in soft lenses market at time of acquisition.

Other acquisitions: Purchased *Iolab Corp.*, a maker of interocular lenses.

Danker Laboratories

Method of entry: Entered de novo (1958). Company makes hard and gas-permeable lenses only.

Acquisitions: Purchased hard lens and solutions business from *Milton Roy* in 1979. May have acquired some technology in gas-permeable lenses through this acquisition.

Dow Corning (Dow Corning Ophthalmics)

Method of entry: Purchase of lens technology from Breger in 1972. Dow Corning itself is a joint venture of Dow Chemical Corp. and Corning Glass; created Dow Corning Ophthalmics to market silicone contact lenses.

Acquisitions: Calcon Labs (1978); thereby obtaining Gelflex, the material used in daily-wear lenses made by Dow Corning. (Currently suing Danker Laboratories for patent infringement as a result of latter's introduction of 100 percent silicone lenses.)

Channel-Lombart

Method of entry: Acquired *Lombart Lenses*, largest maker of hard lenses, from American Sterilizer Corp. in 1982.

Other acquisitions: None.

Rynco Scientific

Method of entry: Entered de novo in 1962. Produce mostly gas-permeable lenses; may also make hard lenses.

Acquisitions: Three, perhaps four small lens manufacturers. CAB (cellulose acetate butyrate) gas-permeable technology may have come from these acquisitions.

Maurice Cunniffe and Rudolf Wood (American Optical Co.)

Method of entry: Acquired *American Optical Co.* in 1982 from Warner-Lambert Corp.

Other acquisitions: American Optical and then-parent Warner-Lambert were licensed for 17 years, beginning in 1973, to make and sell soft contact lenses of material developed by Frigitronics, Inc. Warner-Lambert paid royalties to Frigitronics. When American Optical was sold to Cunniffe and Wood, Frigitronics would not allow Warner-Lambert to automatically transfer licenses to new owners. Until this dispute is settled, American Optical will act as a contractor to Warner-Lambert, who will continue to be responsible to Frigitronics for royalties. Warner-Lambert also is paying 8 percent royalties to NPD.

Frigitronics

Method of entry: Hard lenses—acquisition of *Precision-Cosmet Co.* in 1969; soft lenses—acquisition of *Griffin Labs* (now Frigi-Griffen labs) in 1971. Frigitronics markets both hard and soft lenses through Precision-Cosmet Co.

Other acquisitions: In 1980 acquired *Custom Contact Lens Lab*, maker of hard contact lenses. Some other firms also acquired, possible makers of contact lenses. Also acquired *Bensons* (1969) and *House of Vision* (1982), two optical chains, with a combined total of 400 outlets.

Nestle (Alcon)

Method of entry: Acquired *Alcon* in 1977.

Other acquisitions: Burton Parsons & Co., a maker

of lens care products (1979) and *Scanlens*, a Swedish contact lens maker (1982).

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Appendix C.—Glossary of Terms and Acronyms

Glossary of Terms

Aphakia: The absence of the crystalline lens of the eye, commonly due to the surgical removal of lens cataracts. Aphakia is usually an age-related condition in which the lens transparency is lost. The resulting opaque quality of the lens may diminish vision to light perception only, necessitating surgical intervention.

Astigmatism: A defect of vision usually caused by irregular conformation of the cornea of the eye, because of which light rays fail to meet at a single focal point, resulting in a lack of sharpness or evenness of focus.

Bifocal lenses: Eyeglass or contact lenses divided into two separate focal lengths for near and far vision.

Contact lens: A ground or molded lens of glass or plastic that fits over the corneal portion or more of the scleral surface of the eye, for the purpose of correcting vision problems or for protection.

Cornea: A clear, central portion of the sclera, which serves as the first element in the light focusing system of the eye.

Corneal ulcers: Pits, perforations, or other lesions of the cornea.

Gas-permeable lenses: Contact lenses made of materials through which gases can penetrate so that oxygen can reach the underlying cornea.

Extended-wear lenses: Contact lenses that can be worn for an extended period (e.g., 1 month) because of being made of gas-permeable materials or otherwise constructed so that oxygen can reach the underlying cornea.

Hard lenses: Contact lenses made of rigid, non-gas-permeable plastic materials.

Hydrogel (hydrophilic material): Highly water-absorbent, plastic material from which most soft lenses are made. The most commonly used of these materials is hydroxyethylmethacrylate (HEMA).

Hypermetropia: Same as *hyperopia*.

Hyperopia: Farsightedness; a condition in which visual images come to a focus behind the retina, resulting especially in defective vision of near objects.

Intraocular lens: A lens implanted in the eye to replace the natural lens removed during cataract surgery.

Keratoconus: A pathological condition of the eye in which the cornea becomes distended into a conical or nipple shape.

Monovision: A sight difficulty in one eye only.

Myopia: Nearsightedness; a condition in which the visual images come to a focus in front of the retina, resulting especially in defective vision of distant objects.

Photo-chromatic lenses: Eyeglass lenses that brighten or darken in response to changes in the available surrounding light.

Polymer: A large molecule consisting of a chain of small molecules. Most contact lenses are made from polymer plastics.

Presbyopia: Inelasticity of the lens, which causes difficulty in the viewing of near objects. The condition usually is age related, beginning normally around 45 and continuing until about 70, when it levels off.

Refractive disorders: Conditions of the eye in which the light-bending properties do not provide for clear focusing. Most common among these conditions are myopia (nearsightedness), hypermetropia (farsightedness), and astigmatism.

Retina: A thin tissue consisting of several layers of cells, which contains the light-receptor cells that allow the sense of sight.

Sclera: The elastic coating of connective tissues that covers the eye, including the "white" of the eye.

Single-vision disorder: Hypermetropia, myopia, and other disorders that involve only one type of vision difficulty, rather than presbyopia, which involves difficulties with both near and far vision.

Soft lenses: Contact lenses made of water-absorbing materials. They are more comfortable to wear because of flexibility and gas-permeability, but relatively more difficult to handle and of poorer optical quality than hard lenses.

Spin-casting: A technique for manufacturing contact lenses, in which the lens material, in soft form, is placed in a cup-like mold, and the desired lens curvatures are achieved by spinning the mold at an appropriate speed.

Toric lenses: Contact lenses used to correct for uneven focusing of the eye due to corneal abnormalities.

Trachoma: A chronic, contagious conjunctivitis characterized by the presence of inflammatory granulations on the conjunctival surfaces (the mucous membrane covering the inner surface of the eyelid). These granulations eventually are replaced by scar tissue.

Glossary of Acronyms

CAB —cellulose acetate butyrate
FDA —Food and Drug Administration, U.S. Department of Health and Human Services
FTC —Federal Trade Commission
HEMA —hydroxyethylmethacrylate
IDE —investigational device exemption by FDA
NPD —National Patent Development Corp.
PMMA —polymethylmethacrylate

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